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CONSTITUTIONAL LAW—SACRIFICING THE GOOD OF THE FEW FOR THE GOOD OF THE MANY: DENYING THE TERMINALLY ILL ACCESS TO EXPERIMENTAL MEDICATION

INTRODUCTION

In January of 2008, the Supreme Court denied certiorari on a case that began with the death of a twenty-one year old woman named Abigail Burroughs.¹ In 2001, Abigail lost a two-year fight with squamous cell carcinoma, a type of non-melanoma skin cancer.² Squamous cell carcinoma is the second most common form of skin cancer³—it is estimated to occur domestically in two- to three-hundred thousand people each year.⁴ The American Cancer Society estimates that one- to two-thousand people die each year from skin cancers other than melanoma, including squamous cell carcinoma.⁵ This type of cancer is usually very treatable,⁶ but life threatening when it spreads to a person's organs.⁷

During her treatment, Abigail and her family learned of Erbitux, an experimental cancer drug that demonstrated promising results during early trials.⁸ At the time, Erbitux was in the clinical

1. See *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, (*Abigail Alliance II*), 495 F.3d 695 (D.C. Cir. 2007) (en banc), *cert. denied*, 128 S. Ct. 1069 (2008); Linda Greenhouse, *Justices Won't Hear Appeal on Drugs for Terminally Ill*, N.Y. TIMES, Jan. 15, 2008, at A15.

2. Sue Kovach, *The Abigail Alliance: Motivated by Tragic Circumstances, Families Battle an Uncaring Bureaucracy*, LIFE EXTENSION, Sept. 2007, at 25, 25-26; see also Mark Thornton, Editorial, *The Clinical Trial*, WALL ST. J., Feb. 12, 2007, at A14 (noting the death of Abigail Burroughs due to "a rare form of cancer").

3. Skin Cancer Foundation, Squamous Cell Carcinoma, <http://www.skincancer.org/content/view/23/81> (last visited Apr. 15, 2009).

4. American Cancer Society, What are the Key Statistics About Squamous and Basal Cell Skin Cancer?, http://www.cancer.org/docroot/CRI/content/CRI_2_4_1X_What_are_the_key_statistics_for_skin_cancer_51.asp (last visited Apr. 15, 2009); see also Skin Cancer Foundation, *supra* note 3 (noting that there are "over 250,000 new cases per year estimated in the United States").

5. See American Cancer Society, *supra* note 4 (noting that the number of people who die from squamous cell skin cancer each year is unknown).

6. AM. CANCER SOC'Y, CANCER FACTS & FIGURES 2008, at 19 (2008), <http://www.cancer.org/downloads/STT/2008CAFFfinalsecured.pdf> (characterizing most forms of squamous cell carcinoma as "highly curable").

7. Skin Cancer Foundation, *supra* note 3.

8. Kovach, *supra* note 2, at 26; see also Complaint at 7, *Abigail Alliance for Better Access to Developmental Drugs v. McClellan*, No. 03-1601, 2004 WL 3777340

trial phase of the Food and Drug Administration's (FDA) evaluation process for new drugs.⁹ Abigail was not eligible to participate in the clinical trial,¹⁰ and the manufacturer was unwilling to provide it under the FDA's treatment-use exception.¹¹ Abigail spent the last seven months of her life trying to gain access to Erbitux in the hope that the drug could prolong her life.¹²

In February, 2004, Erbitux was approved "to treat patients with advanced colorectal cancer that has spread to other parts of

(D.D.C. Aug. 30, 2004), *rev'd sub nom.* Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach, 445 F.3d 470 (D.C. Cir. 2006), *vacated en banc*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 128 S. Ct. 1069 (2008); *FDA Extends Indications for Erbitux*, 25 BIOTECHNOLOGY L. REP. 291, 291 (2006) (reporting that the use of Erbitux in clinical trials, along with radiation, "extended patient survival by more than [twenty] months"); Editorial, *Drug Reckoning*, WALL ST. J., Mar. 6, 2006, at A14 (noting that, as early as 2000, an FDA medical reviewer acknowledged there was "extremely compelling" evidence for use of Erbitux in head and neck cancer); Judy Foreman, *For Some, Untested Drug Is a Last Chance*, BOSTON GLOBE, Sept. 23, 2003, at C3 (observing that Iressa, a drug similar to Erbitux, was approved by the FDA in May 2003).

9. Press Release, ImClone Sys. Inc., Data Presented on Anti-Tumor Activity of Erbitux (Cetuximab) as a Single-Agent and in Combination with Widely-Used Three-Drug Chemotherapy in Colorectal Carcinoma (May 19, 2002), <http://phx.corporate-ir.net/phoenix.zhtml?c=97689&p=irol-newsArticle&ID=569027&highlight=> (indicating results from a Phase II clinical trial designed to study the effects of Erbitux on colorectal cancer); *see also* Peter M. Currie, Note, *Restricting Access to Unapproved Drugs: A Compelling Government Interest?*, 20 J.L. & HEALTH 309, 313 (2007) (describing the clinical trial process).

10. Kovach, *supra* note 2, at 26. During Abigail's illness, the clinical trials for Erbitux were being conducted to study its effectiveness for colorectal cancer. *Id.* Abigail Burroughs was ineligible for these trials because she was suffering from head and neck cancer. After Abigail had already died, further clinical trials studied the effects of Erbitux in head and neck cancer. *Id.* at 27; *see also* Complaint, *supra* note 8, at 7 (recounting the clinical trials on the type of cancer that killed Abigail Burroughs); Foreman, *supra* note 8 (noting that Abigail Burroughs was denied access to an experimental cancer drug under a treatment use program because she "had the wrong kind of cancer").

11. *See* Complaint, *supra* note 8, at 6 ("Existing 'compassionate use' programs for new drugs, under which drug companies may opt voluntarily to provide drugs to a limited number of patients during [the] pre-approval period, accommodate only a small number of patients . . . because drug sponsors may not charge more than a cost recovery amount to participants."); PHILIP J. HILTS, PROTECTING AMERICA'S HEALTH: THE FDA, BUSINESS, AND ONE HUNDRED YEARS OF REGULATION 244 (2003) (noting that patients in clinical trials need to be "relatively similar in age, background, and state of disease" in order to be sure "that any result could be clearly attributed to the drug"); *see infra* discussion Part I.A.2 for more information on early access exceptions.

12. Kovach, *supra* note 2, at 26; *see also* Andrew Pollack, *Court Rejects Patient Right to Use Drugs Being Tested*, N.Y. TIMES, Aug. 8, 2007, at A12 ("Abigail [Burroughs] died from cancer after a long battle to receive treatment with experimental drugs that were eventually approved.").

the body.”¹³ Two years later, in 2006, the FDA also approved the use of Erbitux for the treatment of advanced squamous cell carcinoma—the same type of cancer that killed Abigail Burroughs five years earlier.¹⁴ Because of the widely established practice of prescribing drugs off-label, a patient with squamous cell carcinoma could likely have been able to receive this potentially lifesaving drug as early as 2004.¹⁵ The clinical studies of Erbitux have shown that the drug can lower the risk of disease progression and reduce the possibility of death in patients who receive the drug as part of a treatment program that also includes radiotherapy.¹⁶

The Abigail Alliance for Better Access to Developmental Drugs, founded shortly after her death by her father, Frank Burroughs, is a non-profit group that advocates for patients diagnosed with life-threatening illnesses.¹⁷ Its members seek increased access

13. Press Release, U.S. Food and Drug Admin., FDA Approves Erbitux for Colorectal Cancer (Feb. 12, 2004), <http://www.fda.gov/bbs/topics/NEWS/2004/NEW01024.html>; see also *FDA Extends Indications for Erbitux*, *supra* note 8, at 291 (reporting that the FDA approved Erbitux in 2004 for the treatment of colorectal cancer); Editorial, *Erbitux for Americans Too*, WALL ST. J., Dec. 3, 2003, at A16 (noting that in 2003, Switzerland was the first country to approve the sale of Erbitux).

14. See *FDA Extends Indications for Erbitux*, *supra* note 8, at 291; see also U.S. Food and Drug Admin., Erbitux (cetuximab) Approved for Use in Combination with Radiation Therapy, <http://www.fda.gov/cder/Offices/OODP/whatsnew/cetuximab.htm> (last visited Apr. 15, 2009) (noting that Erbitux was approved for use in squamous cell cancers of the head and neck in 2006).

15. See David G. Adams, *The Food and Drug Administration's Regulation of Health Care Professionals*, in 2 FUNDAMENTALS OF LAW AND REGULATION 423, 425 (David G. Adams, Richard M. Cooper & Jonathan S. Kahan eds., 1997) (noting that the “off-label use of approved drugs” is the most notable practice “not subject to regulation under the FDCA”); Steven R. Salbu, *Off-Label Use, Prescription, and Marketing of FDA-Approved Drugs: An Assessment of Legislative and Regulatory Policy*, 51 FLA. L. REV. 181, 186-87 (1999); Richard Miller, Editorial, “Choice” in Health Care, WALL ST. J., Sept. 27, 2007, at A17 (discussing “off-label use of cancer drugs”). A drug prescribed for a use other than the one for which it was approved is prescribed off label. Salbu, *supra* at 188. Drugs may only be marketed for the specific diseases for which they have been approved, but doctors are not similarly regulated by the FDA. *Id.* at 189. In fact, once a drug is approved for use by the FDA, a doctor can prescribe it to a patient for any use. *Id.* at 188.

16. James A. Bonner et al., *Radiotherapy Plus Cetuximab for Squamous-Cell Carcinoma of the Head and Neck*, 354 NEW ENG. J. MED. 567, 572 (2006); see also Marshall R. Posner & Lori J. Worth, *Cetuximab and Radiotherapy for Head and Neck Cancer*, 354 NEW ENG. J. MED. 634 (2006) (noting the “unquestionable improvement in locoregional control, progression-free survival, and overall survival among patients treated with cetuximab plus radiotherapy”); *Drug Reckoning*, *supra* note 8 (reporting that Erbitux tests indicated an increased survival rate of twenty months in cancer patients).

17. Kovach, *supra* note 2, at 30; see also Editorial, *If All Else Fails, Let the Dying Try Unapproved Drugs*, USA TODAY, Aug. 21, 2007, at 10A [hereinafter *If All Else Fails*].

and early-use programs for experimental cancer drugs for patients who have exhausted other available treatment options.¹⁸ In pursuit of this objective, the Alliance submitted a petition to the FDA seeking to amend certain FDA regulations.¹⁹ The proposed changes, which were not enacted by the FDA, would have simplified the process for terminally ill patients to access experimental drugs.²⁰ When the FDA failed to respond favorably to the petition, the Alliance brought its argument to the federal courts.²¹

Part I of this Note will discuss how new “experimental” drugs gain FDA approval, including an overview of the clinical trial process and one of the methods of early access. Part I will also discuss the history of the major drug regulations enacted in the United States, both decisions issued by the court of appeals in the two *Abigail Alliance* cases, as well as the process used by courts to analyze fundamental rights under the due process clause of the Fourteenth Amendment. Part II will analyze how the asserted right was framed in both appellate decisions, the historical inaccuracies that

18. The Abigail Alliance for Better Access to Developmental Drugs, The Abigail Alliance Mission, <http://abigail-alliance.org/mission.htm> (last visited Apr. 15, 2009); see also *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, (*Abigail Alliance II*), 495 F.3d 695, 697 (D.C. Cir. 2007) (en banc), *cert. denied*, 128 S. Ct. 1069 (2008); Foreman, *supra* note 8 (noting that the Abigail Alliance is seeking changes to FDA regulations that would allow terminally ill patients to have wider access to experimental drugs).

19. *Abigail Alliance II*, 495 F.3d at 699; see also Citizen Petition, 21 C.F.R. § 10.30 (2008) (describing the requirements for the submission of a citizen petition to the FDA to seek alterations to existing regulations); FDA Treatment Use of an Investigational New Drug, 21 C.F.R. § 312.34 (describing the treatment-use exception to the clinical trial phase, which the Alliance sought to amend to ease the process for terminally ill patients to gain access to experimental drugs); Citizen Petition of the Abigail Alliance & the Washington Legal Found. to the Food & Drug Admin., U.S. Dep’t of Health & Human Servs. (June 11, 2003), http://abigail-alliance.org/WLF_FDA.pdf [hereinafter Citizen Petition] (detailing the changes that the Alliance was seeking to make to 21 C.F.R. § 312.34); see *infra* Part I. A.1-2 for information regarding the approval process for new drugs and for treatment Investigational New Drugs (IND).

20. *Abigail Alliance II*, 495 F.3d at 699-700; see also Citizen Petition, *supra* note 19; Foreman, *supra* note 8 (noting that the Alliance was seeking a new level of approval—“Tier 1 Initial Approval”—to allow access to experimental drugs that had successfully completed the first phase of the clinical trial process); *infra* notes 53 and 63 for information regarding the Alliance’s proposed changes to the FDA regulations governing access to experimental drugs.

21. *Abigail Alliance for Better Access to Developmental Drugs v. McClellan*, No. 03-1601, 2004 WL 3777340 (D.D.C. Aug. 30, 2004), *rev’d sub nom.* *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470 (D.C. Cir. 2006), *vacated en banc*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 128 S. Ct. 1069 (2008).

the en banc court relied on to support its decision, and alternative considerations that failed to capture that court's attention.

The ultimate conclusion of this Note is that the initial appellate decision²² took the proper approach to the issues presented by the Alliance. Both the Due Process Clause of the Fourteenth Amendment and Supreme Court precedent support the right for mentally competent, terminally ill patients, with no other viable means of treatment, to make reasoned and informed decisions regarding their own treatment. If an individual elects to attempt to prolong his life by undergoing treatment with experimental medications, the FDA should not impose a barrier to access simply because it has not conclusively determined the safety and efficacy of the medication.

I. THE UNDERLYING ISSUES

A. FDA New Drug Approval Process and Treatment Exception

1. New Drug Approval Process

Access to experimental drugs is governed by the Federal Food, Drug, and Cosmetic Act (FDCA),²³ which blocks access to all drugs before they have been approved by the FDA.²⁴ The FDA's approval process requires "substantial evidence"²⁵ that the drug will achieve the effects claimed under its prescribed uses before it can

22. See *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach (Abigail Alliance I)*, 445 F.3d 470 (D.C. Cir. 2006), *vacated en banc*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 128 S. Ct. 1069 (2008).

23. Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. §§ 301-392 (2000).

24. *Abigail Alliance II*, 495 F.3d at 697; see also 21 U.S.C. § 355(a) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application . . . is effective with respect to such drug."); Steven Goldberg, *Technology Unbound: Will Funded Libertarianism Dominate the Future?*, 18 STAN. L. & POL'Y REV. 21, 23 (2007) ("A new drug cannot be marketed until the FDA determines it is safe and effective.").

25. 21 U.S.C. § 355(d)(5). See generally, Geoffrey M. Levitt, James N. Czaban & Andrea S. Paterson, *Human Drug Regulation*, in 2 FUNDAMENTALS OF LAW AND REGULATION, *supra* note 15, at 159-204 (providing a broad overview of the FDA's drug review process).

be sold by manufacturers to the public.²⁶ This evidence is gathered during a lengthy clinical trial process with human subjects.²⁷

Before clinical trials begin on humans, drug companies usually test on laboratory animals to gain an understanding of the drug's effect and potential toxicity.²⁸ Following this research, if the drug is sufficiently promising, the manufacturer will submit an Investigational New Drug (IND) application to the FDA to begin clinical testing on humans.²⁹ After submitting this application, the manufacturer begins the clinical trial process, which is controlled by FDA regulations and requires three phases of clinical trials.³⁰ During these phases, researchers gradually increase the number of humans taking the experimental medication while gathering data concerning the safety and efficacy of the medication.³¹ Phase I focuses primarily on the safety of the drug and its side effects.³² Phases II and

26. See 21 U.S.C. § 355(a); see also Alissa Puckett, Comment, *The Proper Focus for FDA Regulations: Why the Fundamental Right to Self-Preservation Should Allow Terminally Ill Patients with No Treatment Options to Attempt to Save Their Lives*, 60 SMU L. REV. 635, 642 (2007) (discussing the FDCA's prohibition of market access for new drugs prior to FDA approval).

27. *Abigail Alliance II*, 495 F.3d at 697; see Phases of an Investigation, 21 C.F.R. § 312.21 (2008) (describing three phases that investigational new drugs undergo prior to approval by the FDA).

28. Beth E. Meyers, Note, *The Food and Drug Administration's Experimental Drug Approval System: Is it Good for Your Health?*, 28 HOUS. L. REV. 309, 313 (1991); see also 21 U.S.C. § 355(b)(1) (outlining evidentiary requirements necessary for filing an application for a new drug with the FDA); Puckett, *supra* note 26, at 643 ("[F]our levels of testing [are] required before new drugs can receive approval to be marketed in the United States: one on animals and three on humans.").

29. Investigational New Drug (IND) Application, 21 C.F.R. § 312 (2008); see Requirement for an IND, 21 C.F.R. § 312.20; General Requirements for Use of an Investigational New Drug in a Clinical Investigation, 21 C.F.R. § 312.40; see also HILTS, *supra* note 10, at 168 (noting that the submission of the IND "announce[s] a company's intention to begin human experiments with a new drug"); Meyers, *supra* note 28, at 313-14 (explaining IND application process); Puckett, *supra* note 26, at 643 (observing that the results of animal testing will influence the manufacturer's decision to submit a request to the FDA for further approval).

30. 21 C.F.R. § 312.21.

31. *Id.*; see also Meyers, *supra* note 28, at 313-14 (explaining clinical trial and human testing of experimental drugs); Puckett, *supra* note 26, at 643 (noting the number of patients usually involved in each stage of the clinical trial process); Johns Hopkins Kimmel Cancer Center, About Cancer Clinical Trials, <http://www.hopkinskimmelcancercenter.org/index.cfm/cID/240> (last visited Apr. 15, 2009) (describing the clinical trial process and the objectives of the individual phases of the trials).

32. 21 C.F.R. § 312.21(a)(1)-(2) provides:

(a) *Phase 1.*

(1) Phase 1 includes the initial introduction of an investigational new drug into humans. Phase 1 studies are typically closely monitored and may be conducted in patients or normal volunteer subjects. *These studies are designed to determine the metabolism and pharmacologic actions of the drug in humans,*

III are designed to gather information on the drug's safety and effectiveness for treating a particular disease.³³ Progression through these phases can be a lengthy process, often taking six or more years to complete.³⁴

the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. During Phase 1, sufficient information about the drug's pharmacokinetics and pharmacological effects should be obtained to permit the design of well-controlled, scientifically valid, Phase 2 studies. *The total number of subjects and patients included in Phase 1 studies varies with the drug, but is generally in the range of 20 to 80.*

(2) Phase 1 studies also include studies of drug metabolism, structure-activity relationships, and mechanism of action in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes.

Id. (emphasis added); *see also* Foreman, *supra* note 8 (noting that Phase I of the clinical trial process is the "safety trial," and a drug in Phase I may only be tested on several dozen patients).

33. 21 C.F.R. § 312.21(b)-(c) provides:

(b) *Phase 2.* Phase 2 includes the controlled clinical studies conducted to *evaluate the effectiveness of the drug* for a particular indication or indications in patients with the disease or condition under study and to *determine the common short-term side effects and risks associated with the drug.* Phase 2 studies are typically well controlled, closely monitored, and conducted in a relatively small number of patients, *usually involving no more than several hundred subjects.*

(c) *Phase 3.* Phase 3 studies are expanded controlled and uncontrolled trials. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are *intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship* of the drug and to provide an adequate basis for physician labeling. *Phase 3 studies usually include from several hundred to several thousand subjects.*

Id. (emphasis added); *see also* Foreman, *supra* note 8 (noting that Phases II and III of the clinical trial process test the effectiveness and potential dosages of experimental drugs).

34. Elizabeth M. Rutherford, *The FDA and "Privatization"—The Drug Approval Process*, 50 FOOD & DRUG L.J. (SPECIAL ISSUE) 203, 213 (1995); *see also* Geoffrey M. Levitt, James N. Czaban & Andrea S. Paterson, *Human Drug Regulation*, in 2 FUNDAMENTALS OF LAW AND REGULATION, *supra* note 15, at 172 ("The length of FDA review times on [new drug applications] has been a major source of frustration over the years for both the agency and the drug industry."); Mary M. Dunbar, *Shaking Up the Status Quo: How AIDS Activists Have Challenged Drug Development and Approval Procedures*, 46 FOOD DRUG COSM. L.J. 673, 682 (1991) (stating that the approval process for a new drug "can take six years or longer"); A.W. Harris, *Derogating the Precautionary Principle*, 19 VILL. ENVTL. L.J. 1, 71 (2008) ("Perhaps the most prominent example of the harm caused by excessive 'precaution' in regulatory policy is FDA-induced 'drug lag.' The FDA must approve new pharmaceuticals and medical devices before they may be used or prescribed in the United States. The purpose of FDA approval is to ensure that only those drugs deemed 'safe and effective' are approved for use. In a precautionary fashion, the FDA seeks to prevent the release of an unsafe drug. Delaying the availability of potentially life-saving treatment, however, poses risks of its own. Consider the question posed by one prominent FDA critic: 'If a drug that has just been

Following the clinical trial phase of this process, the drug manufacturer submits a New Drug Application (NDA) to the FDA for approval of the new drug.³⁵ This application *must* be approved by the FDA in order for the manufacturer to market the drug.³⁶ Under the FDCA, the FDA has 180 days to respond to the application;³⁷ however, in reality, the approval process can take as long as thirty months.³⁸ If the application fails to meet one of the statutory requirements it will be denied by the FDA.³⁹

2. Clinical Trials and Early Access

Experimental drugs are not generally available to the public during the clinical trial process.⁴⁰ There are, however, two ways that a patient can gain access to experimental drugs during the clinical trial phase.⁴¹ First, if a patient meets the specific require-

approved by FDA will start saving lives tomorrow, then how many people died yesterday waiting for the agency to act?" (quoting Jonathan H. Adler, *More Sorry than Safe: Assessing the Precautionary Principle and the Proposed International Biosafety Protocol*, 35 TEX. INT'L L.J. 173, 195 (2000)); Brian Christopher Moody, *Prescription Medication and Consumer Protection: A Time for Reform*, 5 J. PHARMACY & L. 19, 19 (1996) (estimating that it takes ten to twelve years of development for a drug to reach the market); Puckett, *supra* note 26, at 643 ("[C]ompleting all phases of the required clinical trials takes a minimum of seven years."); Foreman, *supra* note 8 (estimating that it can take up to ten years and \$800 million, on average, for experimental drugs to gain approval); Thornton, *supra* note 2 (noting that clinical testing and FDA approval can take up to seven years).

35. See Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. § 355(a) (2000); see also 21 C.F.R. § 314.50 (outlining the requirements that the application must meet for FDA consideration); HILTS, *supra* note 10, at 168 ("The NDA is a company's application for final approval and marketing of a drug after animal and human tests have been conducted. These applications should contain the most conclusive data proving a new drug is safe and effective.").

36. See 21 U.S.C. § 355(a).

37. *Id.* § 355(c)(1).

38. See Rutherford, *supra* note 34, at 213 ("The FDA averages thirty months to review [New Drug Applications], despite the fact that the statutory review limit is six months."); Stephen R. Kovatis, Note, *The Right to Live: Do the Terminally Ill Have a Constitutional Right to Use Experimental Drugs?*, 26 TEMP. J. SCI. TECH. & ENVTL. L. 149, 152-53 (2007) (stating that it takes six years to complete the clinical trials and an average of thirty months for FDA approval following those trials).

39. See 21 U.S.C. § 355(d); see also Foreman, *supra* note 8 (noting that eighty percent of experimental drugs will not make it through final FDA approval); Rutherford, *supra* note 34, at 213 ("[O]ne in five compounds . . . tested in humans . . . receive FDA approval.").

40. See 21 U.S.C. § 355.

41. Phases of an Investigation, 21 C.F.R. § 312.21 (2008) (clinical trial process); Treatment Use of an Investigational New Drug, 21 C.F.R. § 312.34 (treatment IND); see also Foreman, *supra* note 8 (noting that a patient can gain access to an experimental drug by enrolling in a clinical trial or by requesting access from the manufacturer under a treatment use program).

ments of the drug manufacturer's clinical trial, she *may* be able to receive the drug as a participant in the trial process.⁴² Clinical trials have a limited number of spaces available and gaining access can be difficult because trials are strictly controlled and, in addition to numerous other requirements, mandate that subjects be in certain stages of a disease.⁴³

The second means of early access is an FDA exception that allows patients outside the clinical trial process to access the drug.⁴⁴ This exception, known as a "treatment IND," was introduced in 1987.⁴⁵ The exception provides access to "drug[s] that [are] not approved for marketing," but are under "clinical investigation."⁴⁶ The goal of the exception is to provide potentially lifesaving experimental drugs to needy patients as early as possible.⁴⁷

42. 21 C.F.R. § 312.21. However, even enrollment in a clinical trial does not guarantee that an individual will receive the experimental drug. *See* Goldberg, *supra* note 24, at 23 ("An individual who might benefit from a drug under study might not be chosen for the clinical trials and, in any event, might receive a placebo in those trials."); ClinicalTrials.gov, <http://www.clinicaltrials.gov/> (last visited Apr. 15, 2009) (providing a searchable database of clinical trials).

43. Meyers, *supra* note 28, at 310 (noting that locations for clinical trials may be far from where a willing participant is located); *see also* Puckett, *supra* note 26, at 643 ("[D]rug companies require a patient to be in a certain stage of the disease, at least eighteen years of age, and, in some cases, to not have taken certain drugs or treatments."); *If All Else Fails*, *supra* note 17 (noting that clinical trials "have strict parameters. . . . [and] [o]nly a small percentage of applicants" qualify *if* they have the same disease the experimental drug is being tested for).

44. 21 C.F.R. § 312.34. This exception is by no means the only program operated by the FDA that allows early access to experimental drugs. However, this Note focuses solely on the treatment IND exception because it is representative of the other FDA exceptions and because this is the exception that the Abigail Alliance sought to amend in its Citizen Petition. *See* Citizen Petition, *supra* note 19.

45. Investigational New Drug, Antibiotic, and Biological Drug Product Regulations; Treatment Use and Sale, 52 Fed. Reg. 19,466 (May 22, 1987) (codified at 21 C.F.R. § 312); *see also* Rita Rubin, *Unapproved Drugs Ignite Life-and-Death Debate; Lawsuit Pits Desperately Ill Against Hard Bureaucratic Realities*, USA TODAY, Apr. 2, 2007, 1A (noting that the process of granting access to pre-approved drugs—"compassionate use"—has its foundation in successful efforts by AIDS activists in the 1980s).

46. 21 C.F.R. § 312.34(a). This section provides:

(a) *General. A drug that is not approved for marketing may be under clinical investigation for a serious or immediately life-threatening disease condition in patients for whom no comparable or satisfactory alternative drug or other therapy is available. During the clinical investigation of the drug, it may be appropriate to use the drug in the treatment of patients not in the clinical trials, in accordance with a treatment protocol or treatment IND.*

Id. (emphasis added).

47. *Id.*; *see also* Geoffrey M. Levitt, James N. Czaban & Andrea S. Paterson, *Human Drug Regulation*, in 2 FUNDAMENTALS OF LAW AND REGULATION, *supra* note 15, at 199 (noting that the treatment IND exception allows use of experimental drugs outside a clinical trial to treat patients with qualifying diseases).

Before access to a drug under a treatment IND is granted, the patient's physician must first gain the manufacturer's permission to access the drug.⁴⁸ Next, the patient must submit information to the FDA concerning her clinical history, the proposed treatment plan, and the supplying manufacturer, as well as statements of informed consent and investigator qualifications.⁴⁹ Access is not automatic—the regulations limit access based on the characteristics of the patient and the drug.⁵⁰ A patient with a serious disease, in most situations, can only gain access to experimental drugs that are in Phase III of the clinical trial process.⁵¹ When the patient has an immediately life-threatening disease,⁵² he can potentially gain access to experimental drugs during Phase II, but the regulations indicate that access prior to Phase II ordinarily will not be granted.⁵³

Additionally, the FDA requires that several criteria be met to grant access to experimental drugs under a treatment IND.⁵⁴ First,

48. Physician Request for a Single Patient IND for Compassionate or Emergency Use, U.S. Food and Drug Administration, <http://www.fda.gov/cder/cancer/SingleIND.htm> (last visited Apr. 15, 2009) [hereinafter Physician Request for a Single Patient IND].

49. See 21 C.F.R. § 312.35(b); Physician Request for a Single Patient IND, *supra* note 48 (providing requirements and further contact information for obtaining a treatment IND).

50. See 21 C.F.R. § 312.34(b).

51. See *id.* § 312.24(a) ("In the case of a *serious disease*, a drug ordinarily may be made available for treatment use under this section during Phase 3 investigations or after all clinical trials have been completed; however, in appropriate circumstances, a drug may be made available for treatment use during Phase 2." (emphasis added)). A "serious disease" is not defined in this section of the code, but the definition can be inferred to be any disease that does not meet the definition of an "immediately life-threatening disease."

52. *Id.* § 312.34(b)(3)(ii) ("For the purpose of this section, an 'immediately life-threatening' disease means a stage of a disease in which there is a reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment."); see also Investigational New Drug, Antibiotic, and Biological Drug Product Regulations; Treatment Use and Sale, 52 Fed. Reg. 19,466, 19,467 (May 22, 1987) (codified at 21 C.F.R. pt. 312) (clarifying that the FDA will use a "common sense interpretation" to determine whether there is an "immediate life-threatening disease").

53. 21 C.F.R. § 312.34(a) ("In the case of an *immediately life-threatening disease*, a drug may be made available for treatment use under this section earlier than Phase 3, but ordinarily not earlier than Phase 2." (emphasis added)). The FDA's refusal to grant approval for use of drugs in Phase I is likely justified by the fact that Phase I focuses exclusively on safety, with little attention to effectiveness. See *id.* § 312.21(a)(1) (describing Phase I of the clinical trial process). The Alliance's Citizen Petition sought to allow a treatment IND to be permitted prior to the second phase of the clinical trial process by removing the phrase "but ordinarily not earlier than Phase 2" from 21 C.F.R. § 312.34(a). See Citizen Petition, *supra* note 19, at 3.

54. 21 C.F.R. § 312.34(b).

the requested drug must be intended for the treatment of a “serious or immediately life-threatening disease.”⁵⁵ Second, the patient seeking the drug cannot have any other viable treatment options available.⁵⁶ Third, the treatment IND may only request a drug that is being clinically tested.⁵⁷ Finally, the manufacturer of the drug must be seeking market approval from the FDA for the experimental drug.⁵⁸

If these requirements are met, the regulations indicate that the “FDA *shall* permit” the treatment use of the experimental drug.⁵⁹ However, the FDA can still deny the request for access, even after successful completion of these prerequisites.⁶⁰ If the patient is requesting the drug to treat a serious disease, the request may be denied “for treatment use . . . if there is insufficient evidence of safety and effectiveness to support such use.”⁶¹ Additionally, for a request based on an “immediately life-threatening disease,”⁶² the IND application can also be denied:

[I]f the available scientific evidence, taken as a whole, *fails to provide reasonable basis* for concluding that the drug:

(A) May be effective for its intended use in its intended patient population; or

(B) Would not expose the patients to whom the drug is to be administered to an unreasonable and significant additional risk of illness or injury.⁶³

55. *Id.* § 312.34(b)(1)(i).

56. *Id.* § 312.34(b)(1)(ii) (“There is no comparable or satisfactory alternative drug or other therapy available to treat that stage of the disease in the intended patient population . . .”).

57. *Id.* § 312.34(b)(1)(iii) (“The drug is under investigation in a controlled clinical trial under an IND in effect for the trial, or all clinical trials have been completed . . .”).

58. *Id.* § 312.34(b)(1)(iv) (“The sponsor of the controlled clinical trial is actively pursuing marketing approval of the investigational drug with due diligence.”).

59. *Id.* § 312.34(b)(1) (emphasis added).

60. *Id.* § 312.34(b)(2)-(3).

61. *Id.* § 312.34(b)(2).

62. *Id.* § 312.34(b)(3).

63. *Id.* § 312.34(b)(3)(i)(A)-(B) (emphasis added). This language seems to limit the treatment exception to only those individuals suffering from the specific disease for which the drug has undergone clinical testing. Otherwise, it would be difficult to see how the clinical evidence could provide a “reasonable basis” regarding effectiveness or exposure to additional risks for a disease on which the drug has not been tested. *Id.* The Alliance’s Citizen Petition proposed adding the phrase “taking into account the risk of illness, injury, or death from the disease in the absence of the drug” to 21 C.F.R. § 312.34(3)(i)(B), which the Alliance argued would balance the requirements of the regulation with the individual circumstances of the requesting individual. Citizen Petition, *supra* note 19, at 4.

These restrictions to the treatment IND regulation are at the center of the Alliance's litigation.⁶⁴ The Alliance views these restrictions as ineffective for meeting the needs of terminally ill patients because they "accommodate only a small number of patients" even when the manufacturer is willing to provide the drug.⁶⁵

B. A Fundamental Right or Not a Fundamental Right—That Is the Question

The Alliance's complaint sought to enjoin the FDA "from continuing to enforce a policy that violates the constitutional privacy and liberty rights of terminally ill patients . . . and their constitutional guarantee against deprivation of life without due process."⁶⁶ The district court granted the FDA's motion to dismiss the Alliance's complaint,⁶⁷ which led to the two decisions that are the principle subject of this Note.⁶⁸ Before reviewing those decisions, the following section will provide a brief explanation of the standard fundamental rights analysis.

1. Analyzing Fundamental Rights—The Standard of Review

To determine whether terminally ill patients have a fundamental right to access experimental medication, the *Abigail Alliance* decisions relied on the Supreme Court's analysis in *Washington v. Glucksberg*.⁶⁹ In *Glucksberg*, the Court followed its standard analysis regarding fundamental rights, which begins with an exploration

64. Complaint, *supra* note 8, at 1-2.

65. *Id.* at 6.

66. *Id.* at 1. The Alliance also included in the complaint a count alleging that the "FDA's policy of prohibiting the sale of investigational drugs to willing and mentally competent patients with no other treatment options operates as a death sentence for those patients" because drug manufacturers are unwilling to provide drugs without charge. *Id.* at 10.

67. *Abigail Alliance for Better Access to Developmental Drugs v. McClellan*, No. 03-1601, 2004 WL 3777340, at *12 (D.D.C. Aug. 30, 2004), *rev'd sub nom.* *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470 (D.C. Cir. 2006), *vacated en banc*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 128 S. Ct. 1069 (2008).

68. *See Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, (*Abigail Alliance II*), 495 F.3d 695 (D.C. Cir. 2007) (*en banc*), *cert. denied*, 128 S. Ct. 1069 (2008); *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, (*Abigail Alliance I*), 445 F.3d 470 (D.C. Cir. 2006), *vacated en banc*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 128 S. Ct. 1069 (2008).

69. *Washington v. Glucksberg*, 521 U.S. 702 (1997); *see also Abigail Alliance II*, 495 F.3d at 702 (following the analysis set out in *Glucksberg*); *Abigail Alliance I*, 445 F.3d at 477 (same).

of the “Nation’s history, legal traditions, and practices.”⁷⁰ Since substantive due process issues regularly invoke issues outside of the explicit text of the Constitution, the Court is naturally reluctant to expand on rights when there is a lack of “guideposts for responsible decisionmaking.”⁷¹ History and legal traditions provide the necessary “guideposts” to allow courts to make responsible decisions rather than impose their own policy preferences.⁷² The reliance on these guideposts is important because protecting an asserted right on a constitutional basis will, “to a great extent, place the matter outside the arena of public debate and legislative action.”⁷³

70. *Glucksberg*, 521 U.S. at 710; see, e.g., *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 849-50 (1992); *Cruzan v. Dir., Mo. Dep’t of Health*, 497 U.S. 261, 269-79 (1990); *Moore v. City of E. Cleveland*, 431 U.S. 494, 503 (1977) (plurality opinion).

71. *Glucksberg*, 521 U.S. at 720 (quoting *Collins v. City of Harker Heights*, 503 U.S. 115, 125 (1992)).

72. *Id.* (citing *Moore*, 431 U.S. at 502). In *Moore*, the Court noted that the *Lochner* era provides ample evidence of the dangers in allowing substantive liberties to expand based on “the predilections of those who happen at the time to be Members of [the] Court,” instead of looking to the Constitution and Bill of Rights for guidance. *Moore*, 431 U.S. at 502. However, the impact that AIDS has had on the dynamic between the need for tighter drug regulations and earlier access to drugs could also be grounds for an “emerging awareness” argument for access to experimental drugs. See *Lawrence v. Texas*, 539 U.S. 558, 571-72 (2003) (noting that the “laws and traditions in the past half century” are the most relevant indication of history and tradition (emphasis added)). The “emerging awareness” doctrine recognizes that an asserted right may be fundamental, even without a longstanding history and tradition in this country. Arguably, this is due to shifting beliefs over time concerning what rights are fundamental. This doctrine is in conflict with the normal history and tradition approach to fundamental rights, which examines the nation’s entire history and tradition. See Brian Hawkins, Note, *The Glucksberg Renaissance: Substantive Due Process Since Lawrence v. Texas*, 105 MICH. L. REV. 409, 421 (2006) (noting that the focus on the past half century does not fit the traditional fundamental rights analysis). The “emerging awareness” approach to analyzing the right in *Lawrence* is analogous to the right asserted in *Abigail Alliance*. Experimental drugs were only recognized following the adoption of the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA), and more notably, the ability to regulate for safety was first ushered in under that Act. See Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040 (codified as amended at 21 U.S.C. §§ 301-392 (2000)). Effectiveness did not become a requirement until the 1962 Drug Amendments, at which point the FDA approached its mandate very rigidly. See Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (codified as amended at 21 U.S.C. §§ 301-392); see also *United States v. Rutherford*, 442 U.S. 544 (1979). Since that time, the realities of such an inflexible approach to access to drugs have become increasingly clear. While the FDA still retains control over all experimental drugs, as well as early access to them, it is evident that access to those drugs can mean the difference between life and death. This “emerging recognition” should be an indication that preventing access to experimental drugs infringes the due process rights of terminally ill patients with no other viable treatment option. See *Lawrence*, 539 U.S. at 572.

73. *Glucksberg*, 521 U.S. at 720 (emphasis added). It is important to note that the Court has stated that extending constitutional protection only removes the asserted right from the public discourse “to a great extent”—not entirely. *Id.* This phrasing

In addition to searching for history and traditions to serve as guideposts for the analysis of a fundamental right, a court also looks to see that there is a “careful description” of the liberty interest that is being asserted as fundamental.⁷⁴ In *Abigail Alliance I*, the appellate panel noted that the Supreme Court has not clearly articulated how precisely formulated an asserted right should be.⁷⁵ There is precedent for identifying fundamental rights at the “most specific level at which a relevant tradition protecting, or denying protection to, the asserted right can be identified.”⁷⁶ This relatively restrictive view is mitigated by another view, which holds that “rights not expressed at “the most specific level” [of generality] available’ can nonetheless be recognized.”⁷⁷

At the conclusion of the fundamental rights analysis, if the court determines that there is a fundamental liberty interest at stake, it will subject the infringing statute to strict scrutiny review.⁷⁸

stops short of saying that all public debate ceases when rights are deemed to be fundamental. Indeed, *Roe v. Wade*, 410 U.S. 113 (1973), provides an excellent case study for this proposition. Following more than thirty years and numerous Supreme Court cases, the issue of abortion has remained a contentious topic that the Court continues to revisit. See, e.g., *Gonzalez v. Carhart*, 550 U.S. 124 (2007); *Stenberg v. Carhart*, 530 U.S. 914 (2000); *Planned Parenthood of Se. Pa.*, 505 U.S. 833; *Webster v. Reproductive Health Servs.*, 492 U.S. 490 (1989); Nancy Hopkins, Editorial, *Abortion Rights Linked to Issue of Greater Equality*, THE SUNDAY PATRIOT (Harrisburg, Pa.), Jan. 20, 2008, at F1 (noting that abortion will play a role in deciding the 2008 presidential election); Brody Mullins, *Campaign '08: Planned Parenthood to Push Candidacies*, WALL ST. J., Jan. 22, 2008, at A6A (noting that Planned Parenthood anticipates spending \$10 million to try and persuade one million people to vote for abortion-rights candidates in the 2008 general election).

74. *Glucksberg*, 521 U.S. at 721 (quoting *Reno v. Flores*, 507 U.S. 292, 302 (1993); *Collins*, 503 U.S. at 125; *Cruzan*, 497 U.S. at 277-78).

75. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, (*Abigail Alliance I*), 445 F.3d 470, 477 (D.C. Cir. 2006), *vacated en banc*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 128 S. Ct. 1069 (2008).

76. *Id.* (quoting *Michael H. v. Gerald D.*, 491 U.S. 110, 127 n.6 (1989)).

77. *Id.* at 478 (alteration in original) (quoting *Michael H.*, 491 U.S. at 132 (O'Connor, J., concurring)).

78. See *Glucksberg*, 521 U.S. at 721. The standard of review that a court applies in cases involving a fundamental right is generally strict scrutiny. When the legislation that infringes the fundamental right “comes before the Court,” it is afforded “little presumption of constitutionality.” MILTON R. KONVITZ, *FUNDAMENTAL RIGHTS: HISTORY OF A CONSTITUTIONAL DOCTRINE* 151 (2001). When the right is deemed to be fundamental, only a compelling governmental interest can justify its infringement. *Id.* at 152-53; see also ERWIN CHEMERINSKY, *Constitutional Law: Principles and Policies* 797 (3d ed. 2006) (“If a right is deemed fundamental, the government must present a compelling interest to justify an infringement.”). Further, the methods used to achieve the compelling government interest must be the least restrictive means available, which means that the infringing legislation must be necessary to achieve that interest. CHEMERINSKY, *supra*. A simple showing that a regulation could be achieved in ways

For the infringing regulation to survive strict scrutiny, the regulation must be “narrowly tailored to serve a compelling state interest.”⁷⁹ If the asserted right is not classified as fundamental, the level of review will be rationality review.⁸⁰ Rationality review, a much lower threshold of examination, requires that the regulation provide “a reasonable relation to a legitimate state interest to justify the action.”⁸¹ It is necessary to have these different standards of review in mind when considering the *Alliance I* and *Alliance II* decisions.

2. *Abigail Alliance I*: Early Access as a Fundamental Right

When the Alliance appealed the district court opinion, a divided appellate panel reversed, finding that “a terminally ill, mentally competent adult patient’s informed access to potentially life-saving investigational new drugs . . . warrants protection under the Due Process Clause.”⁸² The court’s inquiry concerned whether terminally ill patients who are mentally competent have a right to ob-

that would be less of an infringement will be sufficient to find the regulation unconstitutional under strict scrutiny review. *See id.* Once strict scrutiny is applied, the burden of establishing that the infringing government action is the least restrictive alternative to meet a compelling interest is a high hurdle that the government is unlikely to meet.

79. *Glucksberg*, 521 U.S. at 721 (internal quotation marks omitted) (quoting *Reno*, 507 U.S. at 302); *see also* CHEMERINSKY, *supra* note 78, at 797 (noting the need for “a compelling interest to justify an infringement” of a fundamental right).

80. *Glucksberg*, 521 U.S. at 722. Conversely, if the right is not determined to be fundamental, a court will apply rationality review, which assumes judicial deference “to the legislative judgment” concerning the regulation. KONVITZ, *supra* note 78, at 150-51; *see also* Roger Pilon, *The New Right to Life*, WALL ST. J., Aug. 10, 2007, at A11 (characterizing the rational basis test as a “judicial abdication” by allowing the government to regulate “as long as it had *any* reason for restricting access”). Under this deferential standard, the infringing government action must only “be a reasonable way to achieve the goal,” and not the least restrictive means of achieving it. CHEMERINSKY, *supra* note 78, at 797. Further, instead of requiring a compelling government interest, only a legitimate government interest is required. If the right asserted is not defined as fundamental by the court, such as the right in *Abigail Alliance II*, the plaintiff must “prove that the government’s restrictions bear no rational relationship to a legitimate state interest.” *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach (Abigail Alliance II)*, 495 F.3d 695, 712 (D.C. Cir. 2007) (en banc), *cert. denied*, 128 S. Ct. 1069 (2008). The *Abigail Alliance II* court noted that “[t]he challenged policy ‘need not be in every respect logically consistent with its aims to be constitutional. It is enough that there is an evil at hand for correction, and that it might be thought that the particular legislative measure was a rational way to correct it.’” *Id.* (quoting *Williamson v. Lee Optical*, 348 U.S. 483, 487-88 (1955)).

81. *Glucksberg*, 521 U.S. at 722.

82. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach (Abigail Alliance I)*, 445 F.3d 470, 486 (D.C. Cir. 2006) (holding 2-1 in favor of a fundamental right of access to experimental drugs by the terminally ill), *vacated en banc*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 128 S. Ct. 1069 (2008).

tain "potentially life-saving post-Phase I investigational new drugs," even if the drugs carry risks for the patient.⁸³

The appeals court applied the fundamental rights analysis of *Washington v. Glucksberg*⁸⁴ and concluded that the ability of an individual to access drugs had not been impaired "throughout the greater part of our Nation's history."⁸⁵ The court indicated that the right asserted by the Alliance could be inferred from the Supreme Court's holding in *Cruzan v. Director, Missouri Department of Health*,⁸⁶ which suggests that liberty provides an individual with a "due process right to refuse life-sustaining medical treatment."⁸⁷ The court provided further justification for its ruling by grounding its analysis in the historical foundation of the common law, which "included the right to self-defense and the right to self-preserva-

83. *Id.* at 472. The court also recognized that terminally ill patients are not acting on their own, but are in consultation with their doctors concerning the potential benefits and hazards that could result from the experimental drugs. *Id.*

84. *Glucksberg*, 521 U.S. at 703 ("The Court's established method of substantive-due-process analysis has two primary features: First, the Court has regularly observed that the Clause specially protects those fundamental rights and liberties which are, objectively, deeply rooted in this Nation's history and tradition. Second, the Court has required a 'careful description' of the asserted fundamental liberty interest." (citations omitted)).

85. *Abigail Alliance I*, 445 F.3d at 472.

86. *Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261 (1990). The petitioners in *Cruzan* were seeking the right to have their daughter removed from artificial nutrition and hydration, which would cause her death. *Id.* at 266-68. Their daughter was permanently incapacitated and in a persistent vegetative state following a car accident. *Id.* The Court, in examining "whether Cruzan has a right under the . . . Constitution which would require the hospital to withdraw life-sustaining treatment," concluded that a state could "require[] . . . evidence of the incompetent's wishes as to the withdrawal of treatment." *Id.* at 269, 280. The individual has the right to refuse medical treatment, but the state has a strong "interest in the protection and preservation of human life," which allowed it to require an evidentiary showing of the incompetent patient's wishes that treatment be withdrawn. *Id.* at 280.

87. *Id.* According to the court of appeals, the right asserted by the Alliance was a naturally inferred proposition based on the right in *Cruzan*:

[T]he Supreme Court in *Cruzan* recognized, in light of the common law and constitutionally protected liberty interests based on the inviolability of one's body, that an individual has a due process right to make an informed decision to engage in conduct, by withdrawing treatment, that will cause one's death. The logical corollary is that an individual must also be free to decide for herself whether to assume any known or unknown risks of taking a medication that might prolong her life.

Like the right claimed in *Cruzan*, the right claimed by the Alliance to be free of FDA imposition does not involve treatment by the government or a government subsidy. Rather, much as the guardians of the comatose patient in *Cruzan* did, the Alliance seeks to have the government step aside by changing its policy so the individual right of self-determination is not violated.

Id. at 484 (footnotes omitted).

tion.”⁸⁸ The court noted that under the common law, there is no general duty to rescue or preserve life, yet interfering with these efforts can create liability.⁸⁹ The court looked at these common law doctrines as evidence of a historical basis for the right to self-preservation.

The court then turned to the history of drug regulation in the United States, concluding that, for the most part, the country lacked drug regulations prior to 1906.⁹⁰ Additionally, the court found that, prior to 1962, there were no regulations that required drug manufacturers to provide evidence of a drug’s effectiveness.⁹¹ The court also focused on the omission of FDA regulations concerning several “aspects of patient access to drugs,” referring specifically to the absence of regulations directed at physicians.⁹² Physicians are able to prescribe drugs “off-label,” which means a physician can prescribe “a drug to a patient for a purpose other than that for which the FDA has approved the use of the drug.”⁹³ According to the court, permitting physicians to prescribe drugs to treat diseases other than those for which they have been approved undermines the FDA’s insistence on the necessity of FDA approval of the drugs’ safety and effectiveness prior to their availability.⁹⁴ Essentially, the court found little distinction between a physician prescribing a drug to treat a disease for which the drug has not been found to be effective and prescribing an experimental drug.

88. *Abigail Alliance I*, 445 F.3d at 480.

89. *Id.* The court viewed the effect of the FDA’s regulations as creating this type of liability. Specifically, the court stated that “[b]arring a terminally ill patient from the use of a potentially life-saving treatment impinges on th[e] right of self-preservation.” *Id.*

90. *Id.* at 481. The court was referring to the Pure Food and Drugs Act of 1906, which introduced, for the first time, regulations pertaining to drugs. See Pure Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (repealed 1938); *infra* Part I.C.1 for information regarding the Pure Food and Drugs Act of 1906.

91. *Abigail Alliance I*, 445 F.3d at 482. There were, however, regulations requiring evidence of safety. *Id.* In 1938, the FDCA was passed, which required that new drugs be proven safe for their intended use. In 1962, this Act was amended to require that new drugs also be proven effective for their intended use. See *infra* Part I.C.2-3 for further discussion on the FDCA and the 1962 Amendments.

92. *Abigail Alliance I*, 445 F.3d at 483. See generally Salbu, *supra* note 15 (providing an in-depth explanation of off-label use); Katherine A. Helm, Note, *Protecting Public Health from Outside the Physician’s Office: A Century of FDA Regulation from Drug Safety Labeling to Off-Label Drug Promotion*, 18 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 117, 152-54 (2008) (defining off-label use).

93. *Abigail Alliance I*, 445 F.3d at 483; see Salbu, *supra* note 15, at 186-88.

94. See *Abigail Alliance I*, 445 F.3d at 483.

The court's final point was based on its perception "that an individual must . . . be free to decide for herself whether to assume any known or unknown risks of taking a medication that might prolong her life."⁹⁵ The court stated: "If there is a protected liberty interest in self-determination that includes a right to refuse life-sustaining treatment, even though this will hasten death, then the same liberty interest must include the complementary right of access to potentially life-sustaining medication, in light of the explicit protection accorded 'life.'"⁹⁶ Clearly, then, the court viewed the right of access to experimental drugs as fundamental, and it remanded the case to the district court to determine whether the FDA's regulation violated this protected liberty interest.⁹⁷

3. *Abigail Alliance II*: Early Access Is Not a Fundamental Right

Rehearing was granted en banc and the full appellate court vacated the decision in *Abigail Alliance I*,⁹⁸ reaffirming the original holding of the district court.⁹⁹ The en banc court viewed the question presented by the Alliance as "whether the Constitution provides terminally ill patients a right to access to experimental drugs that have passed limited safety trials but have not been proven safe and effective."¹⁰⁰ The en banc court concluded that there is no fun-

95. *Id.* at 484.

96. *Id.* at 484-85. The court viewed this as "[t]he logical corollary" to the Supreme Court's determination in *Cruzan* "that an individual has a due process right to make an informed decision to engage in conduct, by withdrawing treatment that will cause one's death." *Id.* at 484.

97. *Id.* at 486.

98. *Id.* at 470.

99. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, (*Abigail Alliance II*), 495 F.3d 695, 697 (D.C. Cir. 2007) (en banc), *cert. denied*, 128 S. Ct. 1069 (2008). The district court determined in *Abigail Alliance for Better Access to Developmental Drugs v. McClellan* that the Alliance's argument did not demonstrate a right that had "a longstanding tradition." Accordingly, it held there was no fundamental right at issue. *Abigail Alliance for Better Access to Developmental Drugs v. McClellan*, No. 03-1601, 2004 WL 3777340, at *10 (D.D.C. Aug. 30, 2004), *rev'd sub nom.* *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470 (D.C. Cir. 2006), *vacated en banc*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 128 S. Ct. 1069 (2008). Again, the court was divided, with the two judges from the earlier decision maintaining that the right asserted was fundamental, and the remaining eight judges holding that the right asserted was not fundamental. See Pollack, *supra* note 12 (recounting the decision to vacate the original appeals court ruling).

100. *Abigail Alliance II*, 495 F.3d at 697. As noted, the issue was initially framed by the panel decision as "whether the Due Process Clause protects the right of terminally ill patients to make informed decisions that may prolong life." *Abigail Alliance I*,

damental right guaranteeing access to experimental drugs that is “deeply rooted in this Nation’s history and tradition.”¹⁰¹

The court began its analysis by reviewing the history and legal traditions related to drug regulation.¹⁰² In response to the Alliance’s assertion that efficacy of drugs was not regulated prior to 1962,¹⁰³ the court concluded that the Alliance failed to contemplate the regulation of drug safety.¹⁰⁴ The regulations challenged by the Alliance prevented access to experimental drugs because they have not been proven *effective* or *safe*.¹⁰⁵ As a result, the en banc court required the Alliance to show a tradition of access to drugs that have not had their safety or effectiveness established by the FDA.¹⁰⁶ In concluding that such a tradition did not exist, the court

445 F.3d at 477; *see also* Pollack, *supra* note 12 (observing the change in the characterization of the right asserted by the Alliance).

101. *Abigail Alliance II*, 495 F.3d at 697 (internal quotation marks omitted) (quoting *Washington v. Glucksberg*, 521 U.S. 702, 720-21 (1997)).

102. *Id.* at 703.

103. *Id.*

104. *Id.* at 703-07. The court concluded that “[d]rug regulation in the United States began with the Colonies and States,” and provided an overview of relevant legislation to support this premise. *Id.* at 704-05. The court first pointed to legislation passed by the Colony of Virginia in 1736 regarding pharmacy as evidence of a long-standing tradition of drug regulation. *Id.* at 705. However, this legislation was “for regulation of the fees and accounts of the practitioners of physic,” and its primary purpose had “no direct relation to the pharmacy laws of today.” EDWARD KREMERS, GEORGE URDANG & GLENN SONNEDECKER, *KREMERS AND URDANG’S HISTORY OF PHARMACY* 158 (4th ed. 1976) (internal quotation marks omitted). In essence, this legislation was designed by highly trained physicians as a means of establishing a tier system of rates that could be charged by individuals based upon their training. *Id.* at 158-59. Those practitioners who attended a university were permitted to charge roughly double the price for their services in dispensing drugs as individuals who were merely apprentices of surgeons or apothecaries. *Id.* at 158. The legislation noted that such apprentices were “very unskillful” and “demand excessive [f]ees,” but mentions *nothing* regarding the safety or efficacy of drugs administered by “apprentices.” *Id.* The legislation only stated that the practice of administering drugs in “greater [q]uantities . . . than are necessary or useful” is “dangerous and intolerable.” *Id.* While there can be no doubt that such practices are particularly troublesome, the statute itself *did not* address drug safety or efficacy, and only targeted the individuals administering medications. *Id.* at 158-59. This suggests that the law was more of a response to interest groups seeking to force their competition out of business. *Id.* Regardless, these laws fall short of making any requirement that drugs must meet specific standards of safety and effectiveness, nor do they lend support for the en banc court’s conclusions.

105. *Abigail Alliance II*, 495 F.3d at 703.

106. *Id.* The court’s focus on safety and effectiveness in this case fails to consider the population on whose behalf the Alliance is advocating. The requirement that drugs be safe and effective serves general public safety concerns, but these concerns are not present within the specific population of terminally ill patients. These patients, whom FDA regulations define as near death, often have nothing to gain from assurances of safety and efficacy. Terminal patients with no other viable treatment options are less

found “that our Nation has long expressed interest in drug regulation, calibrating its response in terms of the capabilities to determine the risks associated with both drug safety and efficacy.”¹⁰⁷

The court then examined the common law doctrines that the Alliance argued in support of its claim of a fundamental right of access to experimental drugs for the terminally ill.¹⁰⁸ The en banc court ruled that: “the doctrine of necessity; . . . the tort of intentional interference with rescue; and . . . the right to self-defense”¹⁰⁹ did not support the Alliance’s argument.¹¹⁰ The court summarized its reasons as follows:

[W]e conclude that the Alliance has not provided evidence of a right to procure and use experimental drugs that is deeply rooted in our Nation’s history and traditions. To the contrary, our Nation’s history evidences increasing regulation of drugs as both the ability of government to address these risks has increased and the risks associated with drugs have become apparent. Similarly, our legal traditions of allowing a necessity defense, prohibiting intentional interference with rescue, and recognizing a right of self-defense cannot justify creating a constitutional right to assume any level of risk without regard to the scientific and medical judgment expressed through the clinical testing process.¹¹¹

Since the court found that the Alliance’s argument failed to establish the existence of a fundamental right, it applied rational basis scrutiny to the Alliance’s claim.¹¹² Examining the regulations under this level of review, the court in *Abigail Alliance II* had little trouble determining that limiting access to experimental drugs serves a legitimate state interest.¹¹³

concerned with the safety or effectiveness of experimental drugs because the alternative is death.

107. *Id.*

108. *Id.* at 707-10.

109. *Id.* at 707.

110. *Id.* at 707-10.

111. *Id.* at 711.

112. *Id.* at 712. Rational basis scrutiny is the lowest level of judicial review that courts will apply in due process cases. This test is applied when the plaintiff is asserting a right that is not fundamental under the Constitution. Government regulation of such a right is permissible so long as there is a legitimate interest for the government’s regulation. See CHEMERINSKY, *supra* note 78, at 797.

113. *Abigail Alliance II*, 495 F.3d at 712 (“[T]he FDA’s policy of limiting access to investigational drugs is rationally related to the legitimate state interest of protecting patients, including the terminally ill, from potentially unsafe drugs with unknown therapeutic effects.”).

C. *The History and Tradition of Safety and Efficacy in Federal Drug Regulations*

The en banc decision placed great emphasis on a lack of history and tradition for unfettered access to experimental drugs.¹¹⁴ However, the court deftly avoided a thorough discussion of the major federal legislation.¹¹⁵ The history of federal drug regulation demonstrates gradual progression toward increased drug testing to ensure that drugs are not harmful. Each step toward tighter controls followed an event that caused public outcry and placed pressure on Congress to limit access to drugs that had not been vetted in a testing process.¹¹⁶ The tightest controls were finally achieved in 1962 with the Kefauver-Harris Amendments (Drug Amendments of 1962).¹¹⁷ Yet, since then, they have faced opposition because the controls block access to certain drugs. In 1988, the FDA amended the regulations to allow some access to the terminally ill to experimental drugs before they were fully approved.¹¹⁸

1. Labeling Concerns and the Pure Food and Drugs Act of 1906

Although the first federal legislation¹¹⁹—enacted in 1848—was designed to provide some general regulation of drugs, the Pure Food and Drugs Act of 1906¹²⁰ is viewed as the initial step toward the tightening of federal control of drugs.¹²¹ Legislation addressing

114. *Id.* at 703-11.

115. *Id.*

116. See PETER TEMIN, *Taking Your Medicine: Drug Regulation in the United States* 29 (1980).

117. Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (codified at 21 U.S.C. §§ 301-392 (2000)).

118. See *infra* Part I.C.4.

119. The earliest federal drug law of note was the Import Drug Act of 1848, which regulated the importation of drugs into the country, a topic outside the scope of this discussion. See Import Drug Act of 1848, 9 Stat. 237; Wesley J. Heath, *America's First Drug Regulation Regime: The Rise and Fall of the Import Drug Act of 1848*, 59 FOOD & DRUG L.J. 169 (2004); Wallace F. Janssen, *Outline of the History of U.S. Drug Regulation and Labeling*, 36 FOOD DRUG COSM. L.J. 420 (1981) (providing a general historical timeline of the FDA and pertinent legislation).

120. Pure Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (repealed 1938).

121. See Joel E. Hoffman, *Administrative Procedures of the Food and Drug Administration*, in 2 FUNDAMENTALS OF LAW AND REGULATION, *supra* note 15, at 14-17 (noting that the Pure Food and Drugs Act was inherently “a law enforcement statute” as opposed to a regulatory one); Note, *Drug Efficacy and the 1962 Drug Amendments*, 60 GEO. L.J. 185, 185 (1971) [hereinafter Note, *Drug Efficacy*] (citing the Pure Food and Drugs Act as the first regulation of a “national scope” directed at drugs).

the purity of food had been submitted to Congress "throughout the 1890s and early 1900s" with each attempt at regulation failing to gain approval.¹²² It was not until 1906, with the publication of Upton Sinclair's *The Jungle*, that "[p]ublic outrage" reached the ears and votes of Congress.¹²³

Operating under its Commerce Clause power, the Fifty-Ninth Congress passed legislation that penalized the "*misbranding and adulteration*" of drugs.¹²⁴ The Act defines "adulterated" as whether, at the time of sale, a drug "differs from the standard of strength, quality, or purity" as certified under testing.¹²⁵ "Misbranded" refers to "all drugs, . . . the package or label of which shall bear any statement, design, or device regarding such article, or the ingredients or substances contained therein which shall be false or misleading in any particular, and to any food or drug product which is falsely branded"¹²⁶ Specifically, drugs were considered misbranded when they were advertised to be something they were not, or when the label was either inaccurate or had omitted statements regarding certain included contents.¹²⁷

122. TEMIN, *supra* note 116, at 28.

123. *Id.* at 28-29; *see also* KREMERS, URDANG & SONNEDECKER, *SUPRA* note 104, at 220 (noting that Upton Sinclair's *The Jungle* helped to push public opinion in favor of federal regulation); UPTON SINCLAIR, *THE JUNGLE* (1906); HARVEY W. WILEY, *THE HISTORY OF A CRIME AGAINST THE FOOD LAW* 266 (Arno Press 1976) (1929) ("'The Jungle,' brought public opinion to the pitch of indignant excitement."); JAMES HARVEY YOUNG, *THE TOADSTOOL MILLIONAIRES: A SOCIAL HISTORY OF PATENT MEDICINE IN AMERICA BEFORE FEDERAL REGULATION* 239 (1961) ("*The Jungle* . . . described the filthy conditions under which America's meat was processed, . . . how rats and the poisoned bread put out to catch them were ground up with meat for public consumption, [and] how employees now and then slipped into steamy vats and next went forth into the world as Durham's Pure Leaf Lard."). *See generally* SINCLAIR, *supra*.

124. KREMERS, URDANG & SONNEDECKER, *supra* note 104, at 220 (emphasis added); *see also* Pure Food and Drugs Act of 1906, Pub. L. No. 59-384, § 1, 34 Stat. 768, 768 (repealed 1938) ("[I]t shall be unlawful for any person to manufacture . . . any . . . drug which is adulterated or misbranded.").

125. Pure Food and Drugs Act of 1906 § 7 (At most, the requirement that a drug not exceed the accepted standard of "strength, quality, or purity" at the time of sale is the only indication under this act that suggests that the drafters were concerned with the safety of drugs.).

126. *Id.* § 8.

127. Section 8 of the Pure Food and Drugs Act of 1906 states:

First. If it be an imitation of or offered for sale under the name of another article.

Second. If the contents of the package as originally put up shall have been removed, in whole or in part, and other contents shall have been placed in such package, or if the package fail to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetani-

These portions of the Pure Food and Drugs Act demonstrate that the Act itself was not designed to promote safety and efficacy of drugs; under the plain meaning of the statute, it was meant “to assure the customer of the identity of the article purchased, not of [the drug’s] usefulness.”¹²⁸ The law did not prevent the individual consumer from self-medicating either, but it did seek to make self-medication safer by requiring drug manufacturers to be truthful about a drug’s contents.¹²⁹ Despite its shortcomings, the 1906 law set the foundation for future drug regulation.¹³⁰

2. Drug Safety and the Federal Food, Drug, and Cosmetic Act of 1938

The deaths of over one hundred people due to the toxic effects of “Elixir Sulfanilamide”¹³¹ led directly to the introduction of the legislation that is currently in force today.¹³² The FDCA took steps to overcome the problems of the 1906 law and give the federal gov-

lide, or any derivative or preparation of any such substances contained therein.

Id.

128. TEMIN, *supra* note 116, at 33; *see also* HILTS, *supra* note 10, at 68 (“The 1906 law was built on the idea that false claims must be prosecuted, rather than addressing the real issues of whether . . . drugs put on the market were safe and worked as they claimed.”); Helm, *supra* note 92, at 126 (“The 1906 Act served its somewhat ‘laissez-faire’ purpose of at least putting the public on notice about the contents of commercially available drug products. It did not, however, address either the safety or efficacy of the drug products, other than in the context of false or misleading claims of therapeutic effect.”).

129. YOUNG, *supra* note 123, at 244; *see also* TEMIN, *supra* note 116, at 22-23 (noting that patients in the late nineteenth century did not need a prescription to obtain a drug, and “[a]ny drug that could be obtained with a prescription could also be obtained without one”). Early regulations were not concerned with drugs, but with licensing of individuals dispensing drugs. TEMIN, *supra* note 116, at 22-23. “[M]edical licensing laws prohibited nondoctors from ‘practising [sic] medicine,’” but they had no effect on the access to drugs by the general public. *Id.* at 23. “Patients did not need to go to a doctor to get a drug; nor were they bound by the doctor’s selection if they did.” *Id.* Members of the public were *free to choose*—among the various drugs available—which ones they wanted to take. *Id.*

130. KREMERS, URDANG & SONNEDECKER, *supra* note 104, at 221.

131. *Id.*; *see also* TEMIN, *supra* note 116, at 42-43 (recounting the “Elixir Sulfanilamide disaster” and the impact it had on the passage of the FDCA); Janssen, *supra* note 119, at 429 (noting that Elixir Sulfanilamide, a “poisonous solvent,” killed over one hundred people). Elixir sulfanilamide was a sulfur drug designed to “treat strep throat and other infections” that also contained a highly toxic substance that was called diethylene glycol. Stephen Mihm, *A Tragic Lesson*, BOSTON GLOBE, Aug. 26, 2007, at 3.

132. TEMIN, *supra* note 116, at 43.

ernment more control over drugs in general.¹³³ The new Act made several important changes that were relevant to the claims of the Abigail Alliance.¹³⁴ Section 505 of the FDCA created, in effect, a class system of drugs by requiring an application for any new drug *prior* to public distribution.¹³⁵ To gain market access under the Act, the manufacturer now needed to produce evidence demonstrating that the drug was safe for use.¹³⁶ New drugs are “[a]ny

133. Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040 (codified as amended at 21 U.S.C. §§ 301-392 (2000)); *see also* H.R. REP. NO. 74-2755, at 3 (1936) (“The measure contains substantially all the features of the old law that have proved valuable in promoting honesty and fair dealing. But it amplifies and strengthens the provisions designed to safeguard the public health and prevent deception . . . and it strengthens the procedural provisions to make more certain the accomplishment of its purpose.”); TEMIN, *supra* note 116, at 42-46 (noting the increased requirements of the regulation over its predecessor, the Pure Food and Drugs Act of 1906); Joel E. Hoffman, *Administrative Procedures of the Food and Drug Administration*, in 2 FUNDAMENTALS OF LAW AND REGULATION, *supra* note 15, at 19 (noting that the Act moved beyond a police function into “direct regulation of the industries within its jurisdiction”).

134. *See* Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach, (*Abigail Alliance I*), 445 F.3d 470 (D.C. Cir. 2006), *vacated en banc*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 128 S. Ct. 1069 (2008).

135. *See* H.R. REP. NO. 75-2139, at 3 (1938) (“A definition of the term ‘new drug’ is provided for the purpose of applying section 505, a provision intended to require adequate testing of new drugs to determine their safety before they are placed on the market.”); TEMIN, *supra* note 116, at 44. This new class of drug is an “experimental drug,” which required evidence of safety prior to approval. Previously, a manufacturer could immediately market the drug. Once the FDA approved the manufacturer’s new drug application, the “experimental” classification of the drug was removed.

136. Federal Food, Drug, and Cosmetic Act § 505:

(a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an application filed pursuant to subsection (b) is effective with respect to such drug.

(b) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such person shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to *show whether or not such drug is safe for use . . .*

Id. (emphasis added). Additionally, the Committee on Interstate and Foreign Commerce reported that:

Section 505 (a) requires new drugs to be adequately tested before they are commercialized. In order to insure that the tests made have been complete, the introduction of a new drug in interstate commerce is prohibited unless the manufacturer has submitted full information showing that the drug has been adequately tested and has *not been found to be unsafe for use under the conditions prescribed in the labeling*. This is not a license provision, but is intended merely to prevent the premature marketing of new drugs not properly tested for safety. . . .

. . . The provision merely sets up a method for the authoritative review of the manufacturer’s tests and *will not unreasonably delay the introduction of new drugs* in the market.

drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as *safe for use under the conditions prescribed*, recommended, or suggested in the labeling thereof”¹³⁷ The 1938 Act imposed safety requirements for the first time but did not address issues of efficacy.

This new law also represented a change in policy.¹³⁸ Under the 1906 Act, consumers were allowed to make their own decisions regarding drugs so long as they had information that correctly described the drug’s composition.¹³⁹ The new law required, in addition to making sure the drug was “safe,” that drug manufacturers provide instructions for using the drug.¹⁴⁰ Although the regulations restricted what drugs made it to the market, the overall “choice of drugs” was still left to the individual consumer, albeit with new efforts geared toward safety.¹⁴¹

3. Drug Effectiveness, the 1962 Drug Amendments, and a Challenge to the “New” Status Quo

The FDCA was given sharper teeth in the early 1960s following three years of congressional investigations.¹⁴² Initially, these investigations focused on problems with testing, marketing, and drug costs, but they culminated at the same time as another drug-related catastrophe.¹⁴³ Late in 1961, an outbreak of phocomelia, a birth defect that causes deformed hands and feet, was reported “with

H.R. REP. NO. 75-2139, at 9 (emphasis added). This statute was the predecessor of what eventually became the IND application. See Joel E. Hoffman, *Administrative Procedures of the Food and Drug Administration*, in 2 FUNDAMENTALS OF LAW AND REGULATION, *supra* note 15, at 23 (classifying Section 505 as a means for the FDA to assert administrative review over the safety tests of a manufacturer).

137. Federal Food, Drug, and Cosmetic Act § 201(p)(1) (emphasis added); see also ESTES KEFAUVER, IN A FEW HANDS: MONOPOLY POWER IN AMERICA 78 (1965) (“The 1938 food and drug law required merely that new drugs, to be cleared for marketing, be proved safe.”); Janssen, *supra* note 119, at 429 (“Drug manufacturers were required to provide scientific proof that new products could be safely used before putting them on the market . . .”).

138. See TEMIN, *supra* note 116, at 45; Joel E. Hoffman, *Administrative Procedures of the Food and Drug Administration*, in 2 FUNDAMENTALS OF LAW AND REGULATION, *supra* note 15, at 19 (shifting from a policing function to a regulatory function).

139. See Pure Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 769 (codified at 21 U.S.C. § 1-15 (2000)) (repealed 1938); TEMIN, *supra* note 116, at 45.

140. See TEMIN, *supra* note 116, at 45; Helm, *supra* note 92, at 127.

141. TEMIN, *supra* note 116, at 45.

142. KEFAUVER, *supra* note 137, at 77-78.

143. *Id.* at 77; see also KREMERS, URDANG & SONNEDECKER, *supra* note 104, at 222 (noting that thalidomide was the cause of birth defects); TEMIN, *supra* note 116, at 123 (discussing thalidomide in Europe); Helm, *supra* note 92, at 128.

alarming frequency in Germany and other European countries.”¹⁴⁴ The source of the outbreak was identified as thalidomide, a popular sleep-aid in Europe that was “widely prescribed off-label to pregnant women” to ease morning sickness.¹⁴⁵ Thalidomide was awaiting approval by the FDA when it was identified as the source of the phocomelia outbreak in Europe.¹⁴⁶

Following the thalidomide disaster, the 1962 amendments increased the FDCA’s drug safety requirements by adding an additional hurdle requiring manufacturers to demonstrate that a drug is effective for a specific purpose.¹⁴⁷ Additionally, the amendment to the 1938 Act altered the definition of “new drug” to “[a]ny drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety *and effectiveness* of drugs, as safe *and effective* for use under the conditions prescribed, recommended, or suggested in the labeling thereof”¹⁴⁸

The 1962 amendments substantially changed the process that drugs undergo before reaching the public. The FDA became actively involved in the approval process and was required to approve new drugs affirmatively before they entered the market.¹⁴⁹ The FDA also pre-approved the testing process employed by manufacturers to demonstrate safety and effectiveness.¹⁵⁰ Moreover, the Drug Amendments of 1962 initiated a revamped version of the

144. TEMIN, *supra* note 116, at 123; *see also* KREMERS, URDANG & SONNEDECKER, *supra* note 104, at 222 (noting that thalidomide “was undergoing widespread and not too tightly controlled clinical trials in the United States”).

145. Helm, *supra* note 92, at 128-29.

146. TEMIN, *supra* note 116, at 123; *see also* Helm, *supra* note 92, at 128 (noting that thalidomide was responsible for birth defects across Europe).

147. Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (codified as amended at 21 U.S.C. §§ 301-392 (2000)); KEFAUVER, *supra* note 137, at 78 (“[D]rugs must be proved efficacious for the conditions for which they are recommended.”); *see also* HENRY G. GRABOWSKI, DRUG REGULATION AND INNOVATION: EMPIRICAL EVIDENCE AND POLICY OPTIONS 15 (1976) (The 1962 Drug Amendments “required firms to provide documented scientific evidence on a new drug’s *efficacy* in addition to the proof of *safety* required by the 1938 act.”). The new requirements of the 1962 amendment also had an impact on the availability of drugs because of the heightened requirement of demonstrating that the drug was effective for treating specific illnesses. OAKLEY RAY & CHARLES KSIR, DRUGS, SOCIETY, AND HUMAN BEHAVIOR 63 (McGraw-Hill Companies, Inc., 8th ed. 1999) (1972); *see also* Janssen, *supra* note 119, at 438 (noting that after the 1962 amendments, safety and effectiveness must be shown with substantial evidence).

148. *See* Drug Amendments of 1962 § 102(a).

149. TEMIN, *supra* note 116, at 125.

150. *Id.*

“New Drug Application,” first established under the 1938 Act, but now with higher standards for safety and effectiveness.¹⁵¹

The new amendments were not welcomed by everyone and spawned litigation regarding access to drugs that failed to meet the new requirements of safety and effectiveness.¹⁵² In *United States v. Rutherford*,¹⁵³ a case strikingly similar to the *Abigail Alliance* cases, the Supreme Court addressed whether the new safety and effectiveness requirements of the FDCA applied to the use of unapproved drugs by terminally ill cancer patients.¹⁵⁴ A group of patients initiated the action to enjoin the FDA from removing the cancer drug Laetrile from the market.¹⁵⁵ Laetrile had been redefined as a new drug after the 1962 amendments took effect, and the absence of “scientific studies of Laetrile’s safety or effectiveness” precluded FDA approval.¹⁵⁶ The Court concluded that terminally ill cancer patients were not a class exempt from the statute’s requirements, and, therefore, they had no right to access drugs that did not meet the new FDCA requirements of safety and effectiveness.¹⁵⁷ The Court refused to “accept the proposition that the safety and efficacy

151. Drug Amendments of 1962 §§ 102-104. The “New Drug Application” process, in its current form, is briefly outlined in Part I.A.1.

152. See Puckett, *supra* note 26, at 645-50 (reviewing other litigation that has challenged the FDA’s new drug approval process).

153. *United States v. Rutherford*, 442 U.S. 544 (1979). *Rutherford* provides further support for the *Abigail Alliance I* decision by noting that the FDCA of 1938 first established safety requirements for new drugs and the 1962 Drug Amendments added effectiveness as a prerequisite to new drug approval. *Id.* at 552. The Supreme Court’s assertion on this point directly contradicts the claim in *Abigail Alliance II* that “at least some drug regulation prior to 1962 addressed efficacy.” *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach (Abigail Alliance II)*, 495 F.3d 695, 706 (D.C. Cir. 2007) (en banc), *cert. denied*, 128 S. Ct. 1069 (2008).

154. *Rutherford*, 442 U.S. at 546; see also FRED H. DEGNAN, FDA’S CREATIVE APPLICATION OF THE LAW: NOT MERELY A COLLECTION OF WORDS 74-78 (2000) (recounting the litigation involving Laetrile and the FDA). While the Court in *Rutherford* was not addressing whether a terminally ill patient had a fundamental right to access experimental medication, the decision set the stage for the *Abigail Alliance* litigation. If the “safety and effectiveness” requirements of the FDCA apply to all persons, not just those with curable diseases, it seems that this precedent would only allow terminally ill patients to access experimental drugs through a due process right.

155. *Rutherford*, 442 U.S. at 548.

156. *Id.* at 549-50.

157. *Id.* at 554; see also Helm, *supra* note 92, at 132 (noting that the Court in *Rutherford* viewed the 1962 amendments as mandating the FDA to prevent market access to drugs whose therapeutic benefit did not outweigh their potential danger); Andrew Bridges, *Dying Patients’ Lawsuit Will Go On: They Want Access to Experimental Drugs that Won’t Be FDA-Approved in Time to Help Them*, ST. LOUIS POST-DISPATCH, May 3, 2006, at A7 (noting that the *Rutherford* Court ruled that there was no exemption in the safety and effectiveness standards of the FDCA for terminally ill patients).

standards of the [FDCA had] no relevance for terminal patients” because it would “deny the [FDA] Commissioner’s authority over all drugs” for the terminally ill.¹⁵⁸ This claim would be addressed anew when the FDA decided to relax the strict preclusion of access prior to its approval of a new drug.¹⁵⁹

4. FDA Rulemaking—Early Access Through the Treatment IND Regulations of 1988

While the chemically induced catastrophes of the early- and mid-twentieth century led to tighter drug regulations,¹⁶⁰ the health epidemics of the late-twentieth century demonstrated the need for greater flexibility. Diseases such as AIDS caused a shift of focus from the safety and efficacy of drugs to the preservation of life, despite the risks of potentially harmful side effects of unproven medications.¹⁶¹

In response to a call for earlier access to promising drugs, the FDA adopted regulations for the treatment use of new drugs undergoing clinical testing.¹⁶² In contrast to the holding in *United States v. Rutherford*, which affirmed the FDA’s strict approach to safety and effectiveness requirements for all drugs, the new regulations

158. *Rutherford*, 442 U.S. at 557. The Court provided additional support for this proposition, arguing that “to exempt from the Act drugs with no proved effectiveness . . . ‘would lead to needless deaths and suffering among . . . patients characterized as “terminal” who could actually be helped by legitimate therapy.’” *Id.* (quoting Laetrile—Commissioner’s Decision, 42 Fed. Reg. 39,768, 39,805 (Aug. 5, 1977)). While it is arguable that this case would be a hindrance to the Alliance’s argument, it is important to remember that the Alliance is seeking access to experimental drugs for those terminally ill patients with *no other viable treatment option* only, and not access that would allow the terminally ill to choose between experimental and generally accepted treatments. See *Abigail Alliance II*, 495 F.3d at 701.

159. See Investigational New Drug, Antibiotic, and Biological Drug Product Regulations; Treatment Use and Sale, 52 Fed. Reg. 19,466, 19,473 (May 22, 1987) (codified at 21 C.F.R. pt. 312).

160. See *supra* text accompanying notes 131-133, 143-146.

161. Michael D. Greenberg, AIDS, Experimental Drug Approval, and the FDA New Drug Screening Process, 3 N.Y.U. J. LEGIS. & PUB. POL’Y 295, 295-96 (2000); see also Geoffrey M. Levitt, James N. Czaban & Andrea S. Paterson, *Human Drug Regulation*, in 2 FUNDAMENTALS OF LAW AND REGULATION, *supra* note 15, at 172 (noting that complaints about drug approval delays from many groups, including AIDS patients, prompted initiatives designed to get drugs to qualifying patients sooner); Goldberg, *supra* note 24, at 26 (“Spurred in part by the AIDS epidemic, faster access to new drugs has been an increasingly popular position for decades.”).

162. Treatment Use of an Investigational New Drug, 21 C.F.R. § 312.34 (2008); see also *supra* notes 40-65 and accompanying text.

took a more lenient approach.¹⁶³ The FDA acknowledged a need for “separate standard[s] for drugs intended to treat immediately life-threatening diseases” based on “the different risk-benefit considerations involved in treating such diseases.”¹⁶⁴ This shift arises from balancing the risks of death from terminal illnesses, such as AIDS, against the goals of the regulations.¹⁶⁵ Early access regulations now provide an avenue for qualified individuals to gain early access to experimental drugs.¹⁶⁶

II. IS ACCESS TO EXPERIMENTAL DRUGS A FUNDAMENTAL RIGHT?

Whether or not the Constitution safeguards proposed rights that are not specifically enumerated is a contentious topic infused with passion and logic.¹⁶⁷ The answer, unequivocally under Su-

163. The logic rejected in *United States v. Rutherford*, “that the safety and efficacy standards of the Act have no relevance for terminal patients,” is consistent with the treatment exception. *Rutherford*, 442 U.S. at 557-58. In the final issued rule, the FDA argued that the treatment exception fits within the holding of the *Rutherford* decision. However, the greater focus on “risk balancing” supports a policy shift by the FDA away from strict interpretation of the new drug requirements to a more flexible approach. See Investigational New Drug, Antibiotic, and Biological Drug Product Regulations; Treatment Use and Sale, 52 Fed. Reg. at 19,473 (noting that the new regulations would *not* conflict with *Rutherford*); DEGNAN, *supra* note 154, at 79 (The treatment IND is “fundamentally at odds with the Supreme Court’s holding in *United States v. Rutherford* in that the new drug approval requirements of the Act apply equally to all drugs, including drugs intended for treating terminal diseases.”).

164. Investigational New Drug, Antibiotic, and Biological Drug Product Regulations; Treatment Use and Sale, 52 Fed. Reg. at 19,468 (rationalizing the intent of the Treatment IND regulation). *But see Rutherford*, 442 U.S. at 549-50 (“The [FDCA] makes no special provision for drugs used to treat terminally ill patients.”); Helm, *supra* note 92, at 133 (clarifying the holding in *Rutherford* as preventing the FDA from “side-step[ping] its own regulations for terminally ill patients and peremptorily opt[ing] for speed over safety”).

165. Greenberg, *supra* note 161, at 349; *see also* Investigational New Drug, Antibiotic, and Biological Drug Product Regulations; Treatment Use and Sale, 52 Fed. Reg. at 19,468 (acknowledging “the different risk-benefit considerations involved in treating [immediately life-threatening] diseases”); DEGNAN, *supra* note 154, at 71. Following the passage of the 1962 Drug Amendments, the FDA manifested an “inflexible interpretation of the provisions.” DEGNAN, *supra* note 154, at 71. However, faced with the realities of modern diseases like AIDS, the FDA has taken “a proactive flexible interpretation” of the requirements of the FDCA. *Id.*

166. *See supra* Part I.A.2 for more information regarding the treatment use of experimental drugs.

167. *See, e.g.,* SOTIRIOS A. BARBER & JAMES E. FLEMING, CONSTITUTIONAL INTERPRETATION: THE BASIC QUESTIONS (2007) (examining various methods of constitutional interpretation); 3 CONSTITUTIONAL LAW AND ITS INTERPRETATION (Jules L. Coleman ed., 1994) (discussing constitutional theory and interpretation); LESLIE FRIEDMAN GOLDSTEIN, IN DEFENSE OF THE TEXT: DEMOCRACY AND CONSTITUTIONAL THE-

preme Court precedent, is yes. The Constitution says nothing concerning the protection of family or reproductive autonomy, sexual activity or orientation, or control over medical decisions—but rights that fall under these general concepts have all been recognized as fundamental.¹⁶⁸ The controversy over the inclusion of these “unenumerated” rights is based on the ideological split between those “who believe that the Court must confine [decisions] to norms clearly stated or implied in the language of the Constitution,” and those “who believe that the Court may protect norms not mentioned in the Constitution’s text”¹⁶⁹ Since these rights are not specifically provided for in the Constitution, the Court must undertake a careful analysis to determine how and why these rights fall under the umbrella of protections that the Constitution gives to individual citizens.¹⁷⁰

The following sections will discuss how proposed fundamental rights are analyzed. First is a discussion of how a potential fundamental right is framed, as well as how the rights in the *Abigail Alliance* cases were framed.¹⁷¹ The discussion will then proceed to the

ORY (1991) (analyzing constitutional theory and arguing in defense of a textualist approach to interpreting the Constitution); JEFFREY M. SHAMAN, *CONSTITUTIONAL INTERPRETATION: ILLUSION AND REALITY* (2001) (reviewing constitutional interpretation throughout different time periods and approaches).

168. CHEMERINSKY, *supra* note 78, at 791-919; *see also, e.g.*, *Lawrence v. Texas*, 539 U.S. 558 (2003) (right to the private sexual activity of consenting adults); *Cruzan v. Dir., Mo. Dep’t of Health*, 497 U.S. 261 (1990) (right of competent adults to refuse medical treatment); *Santosky v. Kramer*, 455 U.S. 745 (1982) (right of parents to have custody of their children); *Roe v. Wade*, 410 U.S. 113 (1973) (right to choose to terminate a pregnancy prior to viability); *Eisenstadt v. Baird*, 405 U.S. 438 (1972) (right to decide whether to bear or beget children); *Loving v. Virginia*, 388 U.S. 1 (1967) (right to marry); *Griswold v. Connecticut*, 381 U.S. 479 (1965) (right to privacy includes matters concerning contraception); *Pierce v. Soc’y of Sisters*, 268 U.S. 510 (1925) (right to control educational upbringing); *cf. Washington v. Glucksberg*, 521 U.S. 702 (1997) (no fundamental right to physician-assisted suicide).

169. ERWIN CHEMERINSKY, *Interpreting the Constitution* 1 (1987); *see also* BARBER & FLEMING, *supra* note 167 (discussing the topic of constitutional interpretation); SHAMAN, *supra* note 167 (discussing different viewpoints of interpretation); Thomas C. Grey, *Do We Have an Unwritten Constitution?*, 27 *STAN. L. REV.* 703 (1975) (examining the differences between pure textual interpretations of the Constitution and those interpretations that delve into inferences derived from the Constitution). *Compare* *Bowers v. Hardwick*, 478 U.S. 186, 194 (1986) (noting that the Supreme Court comes the closest “to illegitimacy when it deals with judge-made constitutional law” that has no connection to “the language or design of the Constitution”), *with* *Griswold*, 381 U.S. at 484 (noting that the Constitution contains “penumbras, formed by emanations from those guarantees that help give them life and substance,” in which the Court has inferred rights that cannot be found within the Constitution’s four corners).

170. *See supra* notes 69-81 and accompanying text.

171. *See infra* Part II.A.

historical guideposts employed by courts to determine whether the defined right is “fundamental.”¹⁷² This section will also discuss the *Abigail Alliance II* court’s erroneous historical analysis of drug regulation, as well as previous Supreme Court conclusions about the history of drug regulation.¹⁷³ This Analysis will ultimately conclude that the *Abigail Alliance II* court misinterpreted and misapplied the fundamental rights analysis, and that a proper application would have enabled the Alliance’s arguments to succeed.¹⁷⁴

A. Carefully Framing Rights into Extinction

Before a court can determine that a government regulation is unconstitutional, it must first conclude that a constitutional right is being infringed. To make this determination, the court must first define the right that is before it. How the asserted right is defined can dramatically sway the outcome of a court’s analysis.¹⁷⁵ Generally, to permit the law to remain consistent and certain, an asserted right must be grounded on some previously recognized right.¹⁷⁶ How broadly a right is defined is an important consideration that can greatly impact a court’s fundamental rights analysis.¹⁷⁷

Defining a previously recognized right in an abstract and broad sense will make it easier for a newly asserted right to fall within recognized precedent; however, an expansive definition could produce undesired consequences, which would sway a court to reject the description urged.¹⁷⁸ At the other end of the spectrum, nar-

172. See *infra* Part II.B.

173. See *infra* Part II.B.1-2.

174. See *infra* Part II.B-C.

175. See *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, (*Abigail Alliance II*), 495 F.3d 695, 716 (D.C. Cir. 2007) (“[T]he description of the right is of crucial importance—too broad and a right becomes all-encompassing and impossible to evaluate; too narrow and a right appears trivial.”), *cert. denied*, 128 S. Ct. 1069 (2008).

176. LAURENCE H. TRIBE & MICHAEL C. DORF, *On Reading the Constitution* 72 (1991); see also Michael J. Gerhardt, *The Role of Precedent in Constitutional Decision-making and Theory*, 60 GEO. WASH. L. REV. 68 (1991) (addressing the various approaches of Supreme Court Justices when confronted with precedent and its role in constitutional decisionmaking); Frederick Schauer, *Precedent*, 39 STAN. L. REV. 571 (1987) (examining the concept of precedent and its impact on judicial decisions).

177. See TRIBE & DORF, *supra* note 176, at 73; Puckett, *supra* note 26, at 659 (noting that if the asserted right is given a narrow definition by the Court, the right is usually not seen as fundamental, while a broader definition will denote a right that is fundamental).

178. See *Abigail Alliance II*, 495 F.3d at 701 n.5 (“If the asserted right is so broad that it protects a person’s efforts to save his life, it might subject to strict scrutiny any government action that would affect the means by which he sought to do so, no matter

rowly interpreting the right can lead to a similar result.¹⁷⁹ If the *asserted* right is described too narrowly, its relation to the precedent rights becomes so tenuous that making the inferential leap from one right to the next becomes impossible. Likewise, if the *precedent* right is interpreted too narrowly, new rights will be unable to fit within its definition.¹⁸⁰

Both *Abigail Alliance* decisions provide an excellent demonstration of how the interpretation of rights can influence a court's holding. In finding support for a fundamental right to experimental drugs, the initial appellate decision focused more attention on the broader assertion that an individual has a right to take steps to preserve her life.¹⁸¹ The focus on preservation of life was based on an ability to make "informed decision[s]" and to "assume . . . known or unknown risks"¹⁸² concerning experimental drugs. This approach focused more on *why* there should be access to experimental drugs.

how remote the chance of success."); *TRIBE & DORF*, *supra* note 176, at 73 ("The more abstractly one states the already-protected right, the more likely it is that the claimed right will be protected under its rubric."); *see also* *Washington v. Glucksberg*, 521 U.S. 702, 724 (1997). Here, the respondents argued that "broad, individualistic principles . . . protect[] the 'liberty of competent, terminally ill adults to make end-of-life decisions free of undue government interference.'" The Court framed the issue as "whether the protections of the Due Process Clause include a right to commit suicide with another's assistance." *Glucksberg*, 521 U.S. at 724.

179. *See* Mark S. Kende, *The Constitutionality of the Death Penalty: South Africa as a Model for the United States*, 38 *GEO. WASH. INT'L L. REV.* 209 (2006) (noting that one of the differences between fundamental rights analysis in South Africa and in the United States is the ability of our courts to achieve a limitation of rights through a narrow interpretation of rights). Narrowly interpreting rights can achieve this result in two ways. First, asserting a new right often requires the use of precedent. By defining a right narrowly, the asserted right can no longer fit within precedent. Second, since courts use evidence of history and tradition to support asserted rights, a court can define a right so narrowly that finding history and tradition in support of the right is nearly impossible.

180. *Id.*

181. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, (*Abigail Alliance I*), 445 F.3d 470, 477 (D.C. Cir. 2006) ("The question presented . . . is whether the Due Process Clause protects the right of terminally ill patients *to make an informed decision that may prolong life*, specifically by the use of potentially life-saving new drugs . . ." (emphasis added)), *vacated en banc*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 128 S. Ct. 1069 (2008). *But see* *Goldberg*, *supra* note 24, at 25 ("Under the court's approach, it will be difficult to find a tradition of government regulation for any new technology.").

182. *Abigail Alliance I*, 445 F.3d at 484. Ultimately, the court concluded that there was a fundamental right under the Due Process Clause of the Fourteenth Amendment that recognizes:

[T]he right of terminally ill patients to make an *informed decision that may prolong life*, specifically by use of potentially life-saving new drugs that the FDA has yet to approve for commercial marketing but that the FDA has de-

In stark contrast, the en banc decision framed the right by focusing on *how* a terminally ill individual would attempt to preserve her life. The court reinterpreted the broader definition suggested by the Alliance,¹⁸³ summarizing it as “whether terminally ill patients have a fundamental right to experimental drugs that have passed Phase I clinical testing.”¹⁸⁴ This narrower definition changed the course of the analysis and limited the ability of the Alliance to rely on the fundamental right set forth in *Cruzan*, which the court also narrowly defined.¹⁸⁵ The en banc court’s narrow definition of the right at issue was an error because the protection of rights under substantive due process concerns the protection of broad concepts, not specific rights. Substantive due process guarantees privacy and liberty. The rights that are found to violate substantive due process are those that infringe on these larger guarantees—for example, the infringement on a pregnant woman’s privacy right in determining whether to terminate her pregnancy prior to the fetus’s viability.¹⁸⁶ It is only by application of these broader concepts that specific actions garner the protection of the Constitution. The *Abigail Alliance II* court failed to observe this, which was readily demonstrated by the Supreme Court in both the *Cruzan* and *Glucksberg* decisions.¹⁸⁷

In *Glucksberg*, the Court clarified the holding of *Cruzan* as a recognition “that the . . . Constitution would grant a competent person a constitutionally protected right to refuse lifesaving hydration

terminated, after Phase I clinical human trials, are safe enough for further testing on a substantial number of human beings.

Id. at 477 (emphasis added).

183. *Abigail Alliance II*, 495 F.3d at 701 (“Whether the liberty protected by the Due Process Clause embraces the *right* of a terminally ill patient with no remaining approved treatment options *to decide*, in consultation with his or her own doctor, whether to seek access to investigational medications that the [FDA] concedes are safe and promising for substantial human testing.” (emphasis added) (alteration in original) (citing Appellants’ Brief at 1, *Abigail Alliance II*, 495 F.3d 695 (04-5350))).

184. *Id.*

185. *Id.* at 711 n.19 (defining the right in *Cruzan* as a “right to refuse lifesaving hydration and nutrition” (internal quotation marks omitted)).

186. See *Roe v. Wade*, 410 U.S. 113, 152-53 (1973) (“[T]he Court has recognized that a right of personal privacy, or a guarantee of certain areas or zones of privacy, does exist under the Constitution. . . . This right of privacy . . . is broad enough to encompass a woman’s decision whether or not to terminate her pregnancy.”).

187. See *Washington v. Glucksberg*, 521 U.S. 702 (1997) (limiting *Cruzan* by not including decisions that would allow an individual to initiate her own death); *Cruzan v. Dir., Mo. Dep’t of Health*, 497 U.S. 261 (1990) (holding that liberty interests allow individuals the right to make decisions regarding their own care).

and nutrition,”¹⁸⁸ which was supported by “the [broader] right of a competent individual to refuse medical treatment.”¹⁸⁹ The Court concluded that assisted suicide fell outside the type of decisions that were deemed fundamentally personal in *Cruzan*.¹⁹⁰ *Glucksberg*’s clarification demonstrates that *Cruzan* recognized a right to make decisions regarding an individual’s medical treatment; yet it limited the decision by excluding the right to intentionally hasten death. The broader fundamental right of *Cruzan*¹⁹¹ was not going to provide a shield for the specific act in *Glucksberg*.¹⁹²

This distinction is important because the *Abigail Alliance II* court failed to invoke the broader concepts of *Cruzan* entirely. Instead, the court relegated its discussion of the precedent to a footnote and focused on the specific medical treatment that the Alliance was ultimately attempting to access.¹⁹³ In *Abigail Alliance II*, the en banc court viewed *Cruzan* as providing a right to refuse treatment, not a right to make a decision regarding treatment, which is arguably inherent in the *Cruzan* Court’s analysis.¹⁹⁴ This micro approach focused specifically on what the petitioner in

188. *Glucksberg*, 521 U.S. at 725 (internal quotation marks omitted) (quoting *Cruzan*, 497 U.S. at 279).

189. *Id.* at 724 (quoting *Cruzan*, 497 U.S. at 277).

190. *Id.* at 705; see also Jessie Hill, *The Constitutional Right to Make Medical Decisions: A Tale of Two Doctrines*, 86 TEX. L. REV. 277, 311 (2008) (noting that the Supreme Court supported a fundamental right “to refuse even life-saving medical treatment” in *Cruzan*, but “declined to extend” this right to medical decisions designed to “hasten death” in *Glucksberg*).

191. *Cruzan*, 497 U.S. 261 (right to refuse treatment and make medical decisions).

192. *Glucksberg*, 521 U.S. 702 (physician-assisted suicide).

193. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, (*Abigail Alliance II*), 495 F.3d 695, 711 n.19 (D.C. Cir. 2007), *cert. denied*, 128 S. Ct. 1069 (2008).

194. *Id.* (characterizing the right in *Cruzan* as “protecting individual freedom from life-saving, but forced, medical treatment”); see also Thomas B. McAfee, *Overcoming Lochner in the Twenty-First Century: Taking Both Rights and Popular Sovereignty Seriously as We Seek to Secure Equal Citizenship and Promote the Public Good*, 42 U. RICH. L. REV. 597, 617 (2008) (noting that the decision in *Cruzan* was grounded in a longstanding “legal tradition protecting the decision to refuse unwanted medical treatment” (emphasis added) (quoting *Glucksberg*, 521 U.S. at 725)); Rahul Rajkumar, *A Human Rights Approach to Routine Provider-Initiated HIV Testing*, 7 YALE J. HEALTH POL’Y L. & ETHICS 319, 348 (2007) (characterizing the decision in *Cruzan* as “a constitutional Substantive Due Process right to make decisions of critical importance to one’s own destiny” (emphasis added)); Puckett, *supra* note 26, at 650 (observing that *Cruzan* and *Abigail Alliance* are both grounded in “the patient’s right to make the decision about her life free from governmental interference” (internal quotation marks omitted) (quoting *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, (*Abigail Alliance I*), 445 F.3d 470, 472 (D.C. Cir. 2006), *vacated en banc*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 128 S. Ct. 1069 (2008))).

Cruzan was seeking, rather than the macro view of why that particular decision was fundamental. The court, therefore, retreated from recognizing the validity of the Alliance's *Cruzan* argument.¹⁹⁵ As a result, the issue was not viewed through the lens of protecting life through personal decisions, but more narrowly as whether there was a right to access experimental drugs.

This characterization denied the Alliance the benefit of *Cruzan*'s previously recognized fundamental right. Instead, under the approach of the *Abigail Alliance II* court, the right asserted by the Alliance would have to stand on its own merits in order to be recognized.¹⁹⁶ The right in *Abigail Alliance II* should properly have focused on the conceptual "why" analysis, and not on the specific "how" analysis. By mischaracterizing the asserted right, the en banc court substantially impaired the entire analysis—and also demonstrated the ease of avoiding many issues under traditional fundamental rights analysis. Fundamentally, the Alliance was not asserting a *right* of access to experimental drugs—it was asserting the existence of an individual *liberty interest* in the protection of life and, ultimately, the decisions regarding life.¹⁹⁷ Not only did *Abigail Alliance II* frame the right too narrowly, it also failed to accurately consider the history of drug regulation.

195. *Abigail Alliance II*, 495 F.3d at 711 n.19.

196. Interestingly, had the en banc court addressed the Alliance's argument under the context of *Cruzan* as it was clarified by the Supreme Court in *Glucksberg*, the Alliance could argue that the type of *decision* they were seeking would fall squarely within the holding of *Cruzan*, without expanding that holding. In *Cruzan*, the Court held that the decision to refuse treatment, which *would lead* to the death of the individual, would be a protected medical decision. *Cruzan*, 497 U.S. 261. Additionally, *Glucksberg*'s guidepost limited *Cruzan* by holding that an individual would not have a right to *cause* his own death. *Glucksberg*, 521 U.S. 702. Reading both cases together, it seems the Court would recognize a fundamental right to make decisions that will result in one's own death, but not decisions made with the express intent to die. The en banc court in *Abigail Alliance* focused on the possibility that experimental drugs *could* cause death (due to limited information on safety and efficacy). *Abigail Alliance II*, 495 F.3d at 706. However, the intent of the Alliance is not to cause death, but to attempt to prevent or delay it. Therefore, the Alliance's argument would not reach as far as the petitioner in *Glucksberg* attempted to take the *Cruzan* analysis (*intent* to cause death). Rather, the Alliance's argument would only *possibly* reach to the extent of *Cruzan* (*certainty* that death would occur).

197. See LARRY YACKLE, *Regulatory Rights: Supreme Court Activism, the Public Interest, and the Making of Constitutional Law* 99-100 (2007) (explaining that under fundamental rights analysis, the right is enforcement of due process, with the real focus being the "liberty interest" the plaintiff is trying to protect); see also *Abigail Alliance I*, 445 F.3d 470 (defining the right as the protection of life); Puckett, *supra* note 26 (arguing that the right that would be provided to the terminally ill is a right of self preservation).

B. *Historical Myths and Questionable Traditions—The En Banc Court's Analysis of Drug Regulations*

The “guidepost” of fundamental rights analysis, according to the Court in *Washington v. Glucksberg*, is the examination of history and tradition, which is used to determine if an asserted right has historically been protected by law.¹⁹⁸ In *Abigail Alliance II*, the court noted that an omission of government regulation or interference throughout history could lend support for a right that is deeply rooted.¹⁹⁹ The absence of regulation is viewed cautiously, however, because “the absence of positive laws encroaching upon a right does not indicate the fundamentality of that right.”²⁰⁰ Conversely, laws that tend to negate the asserted right do not automatically preclude the existence of a fundamental right.²⁰¹ If that were the case, “governments would be free to violate constitutional norms by persisting in a pattern of unconstitutional enactments.”²⁰² Taken together, these observations lead to the conclusion that historical treatment is an ambiguous standard open to numerous methods of interpretation.²⁰³

198. *Glucksberg*, 521 U.S. at 720 (quoting *Collins v. City of Harker Heights*, 503 U.S. 115, 125 (1992)); see also LAURA KALMAN, *THE STRANGE CAREER OF LEGAL LIBERALISM* 198-99 (1996) (“[R]ights and privileges may be presumed to exist, and hence less easily erased, if they can be demonstrated to have been part of the ‘history and traditions of the people.’” (quoting James C. Mohr, *Historically Based Legal Briefs: Observations of a Participant in the Webster Process*, PUB. HISTORIAN, Summer 1990, at 19, 20)). Analysis shows that the recognition of an asserted right as fundamental does not require firm grounding in precedent or statute, but a court must be able to infer that protection is warranted based upon history and legal traditions.

199. *Abigail Alliance II*, 495 F.3d at 706 (“[A] lack of government interference throughout history might be some evidence that a right is deeply rooted.”). But see Erwin Chemerinsky, *History, Tradition, the Supreme Court, and the First Amendment*, 44 HASTINGS L.J. 901, 901 (1993) (“The Court is often explicit in stating that rights should be protected only if there has been a tradition of judicial safeguards . . .”).

200. *TRIBE & DORF*, *supra* note 176, at 99; see also *Abigail Alliance II*, 495 F.3d at 707 (“A prior lack of regulation suggests that we must exercise care in evaluating the untested assertion of a constitutional right to be free from new regulation.”).

201. See *TRIBE & DORF*, *supra* note 176, at 99. But see Chemerinsky, *supra* note 199, at 912 (“[T]he more successful a litigant is in showing widespread, long-term violations of a right, the less likely the Court will protect it because of society’s traditional posture concerning it. . . . [T]he Court uses the absence of historical protection of a right as the basis for refusing current judicial protection.”).

202. *TRIBE & DORF*, *supra* note 176, at 99.

203. See CHRISTOPHER L. EISGRUBER, *CONSTITUTIONAL SELF-GOVERNMENT* 127-28 (2001) (noting that historians are often critical when judges use historical analysis because they use facts subjectively as a means to bolster arguments); KALMAN, *supra* note 198, at 196 (“[L]awyers may favor sweeping interpretations [of history] more than nitpicking historians.”); Chemerinsky, *supra* note 199, at 913 (“The Court picks and chooses from its reading of history and selects those practices that confirm the conclu-

Despite the ambiguities presented by searching for a historical basis on which to ground fundamental rights, the *Abigail Alliance II* court based the crux of its decision on a lack of evidence that the asserted right is “deeply rooted in our Nation’s history and traditions.”²⁰⁴ The following sections will examine the court’s analysis and the fallacy behind its conclusion “that our Nation has long expressed interest in drug regulation.”²⁰⁵ The history of drug regulation, which was outlined in Part I.C., only reflects a series of recent developments during the twentieth century.

1. The Misguided Approach of the *Abigail Alliance II* Court

Because the en banc court framed the issue as a right of “access to experimental drugs,” the analysis focused on whether there was a history and tradition in this country that allowed “access to drugs that have not yet been proven effective” or “safe.”²⁰⁶ In the eyes of the court, the Alliance needed to demonstrate a history of access to unsafe and ineffective drugs, which is clearly an impossi-

sion that it wants to reach.”); Paul Finkelman, *The Constitution and the Intentions of the Framers: The Limits of Historical Analysis*, 50 U. PITT. L. REV. 349 (1989) (examining the ambiguities and shortcomings of historical analysis in interpreting the Constitution); William M. Wiecek, *Clio as Hostage: The United States Supreme Court and the Uses of History*, 24 CAL. W. L. REV. 227, 267 (1988) (noting that the facts that make up history are essentially meaningless without interpretation, which is subjective to the individual historian). This ambiguity is evident “because historical traditions can be indeterminate, and because even when we discover a clear historical tradition it is hardly obvious what the existence of that tradition tells us about the Constitution’s meaning.” *TRIBE & DORF*, *supra* note 176, at 100. *But see* William E. Nelson, *History and Neutrality in Constitutional Adjudication*, 72 VA. L. REV. 1237, 1238-39 (1986) (defending legal “interpretivism” as a method used to interpret the meaning of the Constitution).

204. *Abigail Alliance II*, 495 F.3d at 711; *see also* *TRIBE & DORF*, *supra* note 176, at 98-101 (discussing the ambiguities of historical analysis).

205. *Abigail Alliance II*, 495 F.3d at 703.

206. *Id.* Although the *Abigail Alliance II* court relied heavily on safety and effectiveness, it failed to address the limitations of these standards. The FDCA was not intended to regulate doctors and pharmacists. Off-label use arises when a doctor prescribes an approved medication for a use other than the drug’s designated use. David G. Adams, *The Food and Drug Administration’s Regulation of Health Care Professionals*, in 2 FUNDAMENTALS OF LAW AND REGULATION, *supra* note 15, at 423; Salbu, *supra* note 15, at 188. This reality of drug regulation raises important questions regarding the *Abigail Alliance* litigation. In light of the *Abigail Alliance II* decision, it is difficult to reconcile how medications that have been tested and approved for narrow uses can be used for other, extraneous uses. *See* Miller, *supra* note 15 (noting “that terminally ill patients, especially those with cancer, are treated with experimental drugs all the time” under off-label uses). Drugs being administered for off-label “uses” have not been proven to be safer or more effective for the specific off-label use than a pre-approved and experimental drug has for any use.

ble task.²⁰⁷ Any such argument was doomed to fail because a right to access ineffective and unsafe drugs could not have existed before drugs were tested and labeled as effective and safe.²⁰⁸ The very concept of an “experimental” drug—or an untested drug—did not enter the lexicon of drug legislation until the passage of the FDCA.

Since “experimental” drugs are a relatively recent concept, the court should have focused on the history and tradition of relevant time periods, which would have demonstrated that there is a historical basis for accessing “experimental” drugs that is predicated on a lack of regulation.²⁰⁹ The historical evidence of drug regulation to which the *Abigail Alliance II* court pointed, however, belies its own requirement that the Alliance demonstrate a “tradition of access to drugs that have not yet been proven effective, but also . . . not yet been proven safe.”²¹⁰ Much of the history and tradition referenced in the en banc decision failed to address the court’s assertion of a longstanding history of drug regulation.²¹¹

The *Abigail Alliance II* court pointed to regulations aimed at the qualifications for pharmacists and doctors, but those regulations did not address the safety and efficacy of drugs.²¹² Indeed, “by the 1830’s almost all the states had statutes requiring examination and licensing of *physicians*,” but there is little evidence of legislation

207. Experimental drugs, according to the current FDA regulations, are drugs that have not yet been approved by the FDA. See 21 U.S.C. § 355 (2000). The FDA only approves drugs that have passed the clinical trial process, which requires manufacturers to demonstrate the drug’s safety and effectiveness. *Id.* Therefore, a history and tradition of access to unsafe and ineffective drugs would demonstrate a tradition of access to experimental drugs.

208. See Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (codified as amended at 21 U.S.C. §§ 301-392) (proof of a drug’s effectiveness required after 1962); Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040 (codified as amended at 21 U.S.C. §§ 301-392) (proof of a drug’s safety required after 1938); see also *United States v. Rutherford*, 442 U.S. 544, 552 n.8 (1979) (acknowledging that drug effectiveness was not a requirement prior to 1962 and safety was not required prior to 1938).

209. The court in *Abigail Alliance I* certainly believed that this time period supported the asserted fundamental right. See *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, (*Abigail Alliance I*), 445 F.3d 470, 472 (D.C. Cir. 2006), *vacated en banc*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 128 S. Ct. 1069 (2008). Most importantly, a thorough analysis would demonstrate that the FDCA, while requiring a demonstration of safety for new drugs, was very limited in controlling drug safety prior to the Drug Amendments of 1962. See Federal Food, Drug and Cosmetic Act of 1938.

210. *Abigail Alliance II*, 495 F.3d at 703.

211. *Id.* at 703-07; see *supra* text accompanying note 104.

212. *Abigail Alliance II*, 495 F.3d at 704.

aimed at the safety and efficacy issue.²¹³ The appellate court's conclusion that the "Nation has long expressed an interest in drug regulation" may be accurate, but any resulting legislation did not regulate the safety and effectiveness of drugs.²¹⁴ An "interest in drug regulation" is not the same as evidence of drug regulation, especially when this "interest" is used to justify the constitutionality of regulations that have a dire impact on citizens.²¹⁵

In addition to targeting inappropriate historical indicators in its analysis, the *Abigail Alliance II* court also required a showing of a specific historical basis for access to experimental drugs.²¹⁶ The court viewed any regulation of drugs as a dispositive indicator that there was no right of access to experimental drugs.²¹⁷ However, this treatment overreaches the purpose of turning to historical analysis. History serves as a "guidepost" to fundamental rights analysis—not as a hurdle that must first be passed.²¹⁸ Requiring an affirmative showing that a right has been historically protected presupposes that prior generations would recognize any and all fundamental rights that contemporary generations would recognize. This approach, however, could not realistically confront numerous issues that arise due to technological advances, especially in the area of medicine.

2. The Supreme Court's Recognition of Safety and Effectiveness in Drug Regulation Focuses on the Past Sixty Years.

The Supreme Court's jurisprudence in the area of drug safety further evidences the proper historical analysis of major federal

213. KREMERS, URDANG & SONNEDECKER, *supra* note 104, at 180 (emphasis added). These "new drugs" were considered "experimental" until the limited safety requirements of the 1938 Act were met.

214. *Abigail Alliance II*, 495 F.3d at 703. Furthermore, it has been observed that prior to the FDCA, "consumers could simply buy any nonnarcotic drug they desired," which undermines the appellate court's conclusion concerning drug regulation. TEMIN, *supra* note 116, at 47; *see also supra* text accompanying notes 104 and 129 (providing further analysis of the en banc court's asserted "history").

215. *Abigail Alliance II*, 495 F.3d at 703.

216. The court in *Abigail Alliance II* stated:

[T]o succeed on its claim of a fundamental right of access for the terminally ill to experimental drugs, the Alliance must show not only that there is a tradition of access to drugs that have not yet been proven effective, but also a tradition of access to drugs that have not yet been proven safe.

Id. (emphasis added).

217. *Id.*

218. *Washington v. Glucksberg*, 521 U.S. 702, 721 (1997).

drug regulation that *Abigail Alliance II* should have focused on.²¹⁹ In *United States v. Johnson*, the Court concluded that effectiveness was not required by the Pure Food and Drugs Act of 1906.²²⁰ According to the Court, "misleading statements" concerning the claimed effects of a drug were not considered a misbranding under the Act.²²¹ If misleading claims regarding the effectiveness of drugs were not subject to the provisions of the Pure Food and Drugs Act, it was because the Act was silent on effectiveness and did not intend to regulate the effectiveness of drugs.

Later, in *Weinberger v. Hynson, Westcott & Dunning, Inc.*, the Supreme Court observed that regulation of drug safety and efficacy began with the FDCA and the 1962 drug amendments.²²² In *Weinberger*, the Court examined whether studies for the drug Lutrexin were sufficient to satisfy the effectiveness requirements needed for the continued approval of a new drug application.²²³ The Court acknowledged that prior to 1938 there were no regulations preventing a manufacturer of a new drug from introducing the drug into the

219. See *supra* Part I.C.

220. *United States v. Johnson*, 221 U.S. 488, 495 (1911). In *Johnson*, a drug manufacturer included a claim on the label of the drug "that the contents were effective in curing cancer," which the government argued was misbranding under the Act because the claimed effectiveness could not be substantiated. *Id.* The Court concluded that the language of the act was not intended to cover "all possible false statements." *Id.* at 497. According to the Court's interpretation, Congress "was much more likely to regulate commerce in food and drugs with reference to plain matter of fact . . . than to distort the uses of its constitutional power to establishing criteria in regions where opinions are far apart." *Id.* at 498. In delivering the opinion of the Court, Justice Holmes implied that the "claims were stated to be opinions, which were not capable of being proven right or wrong" and thus were "protected by the constitutional guarantees of freedom of speech." TEMIN, *supra* note 116, at 33.

221. *Johnson*, 221 U.S. at 496.

222. *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973).

223. *Id.* at 615-16. The New Drug Application (NDA) requirement under the original act was a much more liberal requirement than it is under its current form:

This NDA was to include "full reports of investigations which have been made to show whether or not such a drug is safe for use." If the submitted paperwork was satisfactory, the application was allowed to become effective. Between 1938 and 1962 about 13,000 NDAs were submitted and about 70 percent were allowed to be marketed.

RAY & KSIR, *supra* note 147, at 62. The NDA requirement under the original act served more as a rubber stamp for drug companies than as a protection for the general public. See Joel E. Hoffman, *Administrative Procedures of the Food and Drug Administration*, in 2 FUNDAMENTALS OF LAW AND REGULATION, *supra* note 15, at 43 (noting that *Weinberger* dealt primarily with "applying the effectiveness requirements of the 1962 Drug Amendments to previously approved prescription drugs" as a basis for removing FDA approval for pre-approved drugs).

marketplace.²²⁴ Additionally, the FDCA “provided for regulatory clearance of drugs prior to marketing . . . in the interests of public safety,”²²⁵ and that “the 1938 Act permitted evaluation of a new drug *solely on the grounds of its safety*.”²²⁶ It was not until the 1962 drug amendments that the FDA had the authority to “evaluate drugs for *effectiveness* as well as safety.”²²⁷ At this point, the FDA became a “gatekeeper” to market access of new drugs.²²⁸

The *Abigail Alliance II* court asserted that the Alliance’s argument concerning the effectiveness of drugs failed because, “as a matter of history, at least some drug regulation prior to 1962 addressed efficacy” and “an arguably limited history of efficacy regulation prior to 1962 does not establish a fundamental right of access to unproven drugs.”²²⁹ The court, however, provided no examples of regulations concerning the effectiveness of drugs in support of this assertion, and only acknowledged “that Congress and the FDA have continually responded to new risks,” and that “[r]ecent government efficacy regulation has reflected Congress’s exercise of its well-established power to regulate”²³⁰ The court also failed to take into consideration the efforts made to ease the effect of the hurdles placed on access to unapproved drugs.²³¹

224. *Weinberger*, 412 U.S. at 623; *supra* notes 119-129 and accompanying text.

225. *Weinberger*, 412 U.S. at 623; *see also* RAY & KSIR, *supra* note 147, at 62 (“A critical change in the 1938 law was the requirement that *before* a new drug could be marketed its manufacturer must test it for toxicity.”).

226. *Weinberger*, 412 U.S. at 615 (emphasis added). *But see* Janssen, *supra* note 119, at 438 (arguing that effectiveness requirements had been around since the Massachusetts Bay Colony in 1630).

227. *Weinberger*, 412 U.S. at 630 (emphasis added); *see also* RAY & KSIR, *supra* note 147, at 63 (“The most important change was one requiring that every new drug be demonstrated to be *effective* for the illnesses mentioned on the label.”); U.S. Food and Drug Administration, Milestones in U.S. Food and Drug Law History, <http://www.fda.gov/opacom/backgrounders/miles.html> (last visited Apr. 15, 2009) (“Kefauver-Harris Drug Amendments passed to ensure drug efficacy and greater drug safety. *For the first time, drug manufacturers are required to prove to FDA the effectiveness of their products*” (emphasis added)). *But see* Note, *Drug Efficacy*, *supra* note 121, at 186 (noting that “the Food and Drug Act of 1906 was amended in 1912 to declare drugs making fraudulent claims of efficacy to be misbranded” in response to the Supreme Court decision in *United States v. Johnson*, 221 U.S. 488, 498 (1911)).

228. RAY & KSIR, *supra* note 147, at 62.

229. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach (Abigail Alliance II)*, 495 F.3d 695, 706 (D.C. Cir. 2007) (en banc), *cert. denied*, 128 S. Ct. 1069 (2008).

230. *Id.*

231. *See supra* notes 161-165 and accompanying text (discussing the 1988 Drug Amendments); *see also* Greenberg, *supra* note 161, at 334 (“The FDA’s new drug approval regime . . . [is] focused on making experimental drugs available more rapidly, both on a pre-approval and post-approval basis.”).

Johnson, *Weinberger*, and *Rutherford* may not support the Alliance's argument, but these cases certainly dilute the rationale of the en banc court's decision.²³² The court's analysis of history and tradition ignored many key factors necessary for a comprehensive analysis of the right at issue. If the en banc court had approached the analysis more thoroughly, it would have discovered a void in regulations during the first half of our nation's existence. That period was followed by the gradual tightening of control, which led to litigation over access to various drugs.²³³

C. *The Right Asserted Falls Under the Umbrella of Cruzan and Should Be Recognized as Fundamental*

The Abigail Alliance, as well as the initial appeals court decision, characterized the asserted right as analogous to the fundamental right recognized in *Cruzan v. Director, Missouri Department of Health*.²³⁴ The *Abigail Alliance I* court concluded that the liberty precedent of the Supreme Court "indicates that the right claimed by the Alliance can be inferred from the Court's conclusion in *Cruzan* . . . that an individual has a due process right to refuse life-sustaining medical treatment."²³⁵ If individuals have the right to make decisions and take risks that would *clearly* lead to their deaths, then they also have the right to make decisions and assume risks that *might* lead to their deaths.

The *Cruzan* Court stated that "[t]he choice between life and death is a *deeply personal decision* of obvious and overwhelming finality," which allowed the state to impose requirements to protect that choice.²³⁶ In supporting this decision, the Court determined that a state can require elevated evidentiary requirements of the intent of the patient as a means to protect the "personal element"

232. See *United States v. Rutherford*, 442 U.S. 544, 552 (1979) (recognizing that the 1962 Drug Amendments first established requirements for drug effectiveness and the FDCA of 1938 first required evidence of safety); *Weinberger*, 412 U.S. at 612-14 (noting that drug regulations did not begin examinations for safety prior to 1938 and effectiveness prior to 1962); *Johnson*, 221 U.S. 488 (arguing that the Pure Food and Drugs Act of 1906 did not require that a drug be effective).

233. See discussion *supra* Part I.B-C.

234. *Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261 (1990); see *supra* note 86 for a discussion of the fundamental right at issue in *Cruzan*.

235. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, (*Abigail Alliance I*), 445 F.3d 470, 472 (D.C. Cir. 2006), *vacated en banc* 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 128 S. Ct. 1069 (2008).

236. *Cruzan*, 497 U.S. at 281 (emphasis added).

of the choice.²³⁷ In recognizing that “the choice between life and death” is “deeply personal,” the Court set these types of decisions apart as ones that should be left up to the individual.²³⁸

To support its holding, the Court in *Cruzan* noted that an intrusion into one’s body without consent is an assault, which creates liability in the perpetrator.²³⁹ The requirement of informed consent, which is a basic fixture in American law, leads to “[t]he logical corollary . . . that the patient generally possesses the right not to consent.”²⁴⁰ Simply put, if a doctor is required to obtain a patient’s informed consent prior to administering treatment, the patient is equally free to withhold consent. It is the consent of the patient that is the dispositive factor regarding treatment. The bodily integrity doctrine was recognized by the *Cruzan* Court as a longstanding principle that “[n]o right is held more sacred, or is more carefully guarded, by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law.”²⁴¹ The right the Alliance argued for rises to the level of that described by the Court in *Cruzan* and should likewise be recognized.²⁴²

The Alliance sought a decision that is remarkably analogous to *Cruzan*—there are only a few minor conceptual differences. The first conceptual difference, and the most limiting to the Alliance’s case, is the foundation on which the *Cruzan* case was based. The *Cruzan* Court pointed to a common law right to bodily integrity, which includes a requirement of a patient’s informed consent.²⁴³ The Alliance lacks an analogous common law right according to the appellate court.²⁴⁴ A second difference is the type of government

237. *Id.* Ironically, instead of allowing the government to take measures to preserve a terminally ill patient’s decision, which was the concern of the Court in *Cruzan*, the court in *Abigail Alliance II* allowed the government to prevent the patient’s right to make such a decision. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach (Abigail Alliance II)*, 495 F.3d 695 (D.C. Cir. 2007) (en banc), *cert. denied*, 128 S. Ct. 1069 (2008).

238. *Cruzan*, 497 U.S. at 281.

239. *Id.* at 269.

240. *Id.* at 270.

241. *Id.* at 269 (alteration in original) (quoting *Union Pac. Ry. Co. v. Botsford*, 141 U.S. 250, 251 (1891)).

242. *See id.*

243. *Id.*

244. *See Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach (Abigail Alliance II)*, 495 F.3d 695, 707 (D.C. Cir. 2007) (en banc), *cert. denied*, 128 S. Ct. 1069 (2008). The Alliance argued that the common law doctrine of

action at issue. Under *Cruzan*, the government would be standing aside while the terminally ill patient refused treatment, while *Abigail Alliance* would require the government to stand aside while the terminally ill patient received treatment from a willing drug manufacturer.

Additionally, there is another minor, but notable difference between the Alliance's asserted right and the right delineated by the Supreme Court in *Cruzan*. In *Cruzan*, the right permitted would allow an individual to dictate his own treatment and make a decision that *would* result in death.²⁴⁵ The Alliance is seeking treatment that *could* result in death. The premise of *Cruzan* is that an individual can refuse viable treatments while the Alliance seeks the ability to obtain further treatment when all viable treatments are extinguished. *Cruzan* permits an individual to dictate the measures that may be taken to sustain his life. *Abigail Alliance II* limits those measures if they are based on experimental medications.

This is an inconsistent result. If *Cruzan* allows an individual to refuse treatments that sustain life, thereby choosing death, then an individual should also be permitted to seek treatments that may sustain life. Since "[t]he choice between life and death is a deeply personal decision of obvious and overwhelming finality," the individual should be permitted to choose how to face death—either resolved to the "finality," or by pursuing all potentially lifesaving actions.²⁴⁶ The FDA should be concerned with the safety and efficacy of drugs, but not act as a barrier to treatments that could produce positive results for an individual whose death is certain without such treatment.

Cruzan ultimately stands for allowing a competent person to make an *informed* decision that she understands will lead ultimately to her death.²⁴⁷ The decision in *Abigail Alliance II* limits the choices for a terminally ill individual to FDA-approved medications. The en banc court has determined that a decision can only be *informed* if the FDA determines that the drugs sought are safe and effective.²⁴⁸ A decision based on the best available information is

necessity, the tort of intentional interference with rescue, and the right to self-defense lead, conceptually, to a right of self-preservation, which has its roots in the common law. The en banc court, however, dismissed these common law duties as failing to provide support for a fundamental right to access experimental medication. *Id.* at 707-10.

245. *Cruzan*, 497 U.S. at 281.

246. *Id.*

247. *See id.*; *supra* text accompanying note 196.

248. *See Abigail Alliance II*, 495 F.3d at 703. The court in *Abigail Alliance II* arrived at the conclusion that terminally ill patients do not have a fundamental right to

not sufficient to meet the requirements of the en banc court. In essence, the court added another requirement—the decision must be informed *and* FDA-approved.

The *Abigail Alliance II* court acknowledged that the purpose of Phase I of the clinical trial process is designed in large part to “gather[] data on effectiveness” and that the “primary focus is to determine whether the drug is safe enough for continued human testing.”²⁴⁹ The court deferred to the judgment of the FDA concerning what level of risk the individual patient should be willing to accept with an end-of-life decision. The premise of *Cruzan* logically leads to the ability of a terminally ill patient, with no other viable treatment option, to make a decision based on the information available to him at the time the decision is made.

CONCLUSION

The FDA regulations governing the availability of experimental drugs achieve important state purposes. They ensure safety and efficacy and hold manufacturers accountable for the drugs they produce. Indeed, it is these important purposes that fuel opposition to the type of access that the Alliance is attempting to gain.²⁵⁰ These regulations, however, impose burdens on terminally ill people whose lives literally depend on access to new medications that could prove to be lifesaving. The initial appellate decision, *Abigail Alliance I*, found, through sound reasoning, “that an individual must . . . be free to decide for herself whether to assume any known or unknown risks of taking a medication that might prolong her life.”²⁵¹ This is especially important for terminally ill patients, whose circumstances drastically alter the balance between the potential benefits and the detriments of that treatment.

It is true that experimental medications will not always result in a benefit to a terminally ill patient. Yet, experimental treatments have worked miracles. Take, for example, the recent story of professional football player Kevin Everett. On September 9, 2007, Kevin made a tackle during a game and suffered a “fracture

the access of experimental drugs because those drugs have not been proven safe or effective for their intended purpose. *Id.*

249. *Id.* at 698 (citing Phases of an Investigation, 21 C.F.R. § 312.21(a)(1) (2008)).

250. Foreman, *supra* note 8 (noting that providing access to experimental drugs would undermine the system of ensuring drug safety and efficacy).

251. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, (*Abigail Alliance I*), 445 F.3d 470, 484 (D.C. Cir. 2006), *vacated en banc*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 128 S. Ct. 1069 (2008).

dislocation of [his] cervical vertebrae”—an injury that usually results in paralysis.²⁵² Kevin was treated with controversial and groundbreaking medical care, which may have played a significant role in his ability to walk again.²⁵³ The treatment he received has not been proven safe, and its effectiveness is not certain because of the additional care he received for his injury. Equally unknown, of course, is what condition he would be in today if the experimental treatment had not been provided.

The choice by a terminally ill individual to undergo treatment using currently unproven medications is no different from other medical choices protected as fundamental rights—and the risks are often the same. By denying terminally ill individuals the right to access potentially lifesaving medications, the government is making the individual's choice for her, rather than giving her the freedom to make her own choice. Instead of recognizing that a person has a right to fend off death by trying every possible cure, the FDA regulations remove options that would give hope to those who need it most. Indeed, it is difficult to imagine what risks would outweigh any potential benefits when the only other alternative is death. Regardless, the decision to accept these risks should be vested in the individual and not the government.

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252. Tim Layden, *Kevin Everett: The Road Back*, SPORTS ILLUSTRATED, Dec. 17, 2007, at 57, 58, 62.

253. *Id.* at 58.